BEST AVAILABLE IMAGES

Defective images within this document are accurate representation of The original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PC[redacted]

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

[redacted]eiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference D 1903-1 WO
(if desired) (12 characters maximum)

Box No. I TITLE OF INVENTION

INHALATION DEVICE

Box No. II APPLICANT

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Astra Aktiebolag
S-151 85 Södertälje
Sweden

☐ This person is also inventor.

Telephone No.
+ 46 8 553 260 00

Facsimile No.
+ 46 8 553 288 20

Teleprinter No.

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Von Schuckmann, Alfred
Winnekendonker Strasse 52
D-47627 Kevelaer
Germany

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: DE

State *(that is, country)* of residence: DE

This person is applicant for the purposes of: ☒ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

Intellectual Property, Patents
Astra Aktiebolag
S-151 85 Södertälje
Sweden

Telephone No.
+ 46 8 553 260 00

Facsimile No.
+ 46 8 553 288 20

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Sheet No. .....

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Ullbrand, Björn
Astra Draco AB
Box 24
S-221 00 Lund
Sweden

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Selmer, Anders
Astra Draco AB
Box 24
S-221 00 Lund
Sweden

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: SE

State *(that is, country)* of residence: SE

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

- [X] AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- [X] EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- [X] EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- [X] OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- [X] AL Albania
- [X] AM Armenia
- [X] AT Austria and utility model
- [X] AU Australia
- [X] AZ Azerbaijan
- [X] BA Bosnia and Herzegovina
- [X] BB Barbados
- [X] BG Bulgaria
- [X] BR Brazil
- [X] BY Belarus
- [X] CA Canada
- [X] CH and LI Switzerland and Liechtenstein
- [X] CN China
- [X] CU Cuba
- [X] CZ Czech Republic and utility model
- [X] DE Germany and utility model
- [X] DK Denmark and utility model
- [X] EE Estonia and utility model
- [X] ES Spain
- [X] FI Finland and utility model
- [X] GB United Kingdom
- [X] GE Georgia
- [X] GH Ghana
- [X] GM Gambia
- [X] GW Guinea-Bissau
- [X] HR Croatia
- [X] HU Hungary
- [X] ID Indonesia
- [X] IL Israel
- [X] IS Iceland
- [X] JP Japan
- [X] KE Kenya
- [X] KG Kyrgyzstan
- [X] KP Democratic People's Republic of Korea
- [X] KR Republic of Korea
- [X] KZ Kazakhstan
- [X] LC Saint Lucia
- [X] LK Sri Lanka
- [X] LR Liberia
- [X] LS Lesotho
- [X] LT Lithuania
- [X] LU Luxembourg
- [X] LV Latvia
- [X] MD Republic of Moldova
- [X] MG Madagascar
- [X] MK The former Yugoslav Republic of Macedonia
- [X] MN Mongolia
- [X] MW Malawi
- [X] MX Mexico
- [X] NO Norway
- [X] NZ New Zealand
- [X] PL Poland
- [X] PT Portugal
- [X] RO Romania
- [X] RU Russian Federation
- [X] SD Sudan
- [X] SE Sweden
- [X] SG Singapore
- [X] SI Slovenia
- [X] SK Slovakia and utility model
- [X] SL Sierra Leone
- [X] TJ Tajikistan
- [X] TM Turkmenistan
- [X] TR Turkey
- [X] TT Trinidad and Tobago
- [X] UA Ukraine
- [X] UG Uganda
- [X] US United States of America
- [X] UZ Uzbekistan
- [X] VN Viet Nam
- [X] YU Yugoslavia
- [X] ZW Zimbabwe

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- [ ] GD Grenada
- [ ] IN India

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) (22.12.97) 22 December 1997	19757207.3	DE		
item (2) (22.12.97) 22 December 1997	19757208.1	DE		
item (3)				

☐ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): _____

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*: ISA / EP

Request to use results of earlier search: reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*: Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII CHECK LIST: LANGUAGE OF FILING

This international application contains the following number of sheets:

request	:	4
description (excluding sequence listing part)	:	32
claims	:	5
abstract	:	1
drawings	:	25
sequence listing part of description	:	
Total number of sheets	:	67

This international application is accompanied by the item(s) marked below:

1. ☐ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Keith Boden

Boden, Keith McMurray
Intellectual Property, Patents, Astra Aktiebolag

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

CORRECTED VERSION

PCT

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

To:

ASTRAZENECA AB
Intellectual Property, Patents
S-151 85 Södertälje
SUÈDE

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

Date of mailing (day/month/year) 07 June 2000 (07.06.00)	
Applicant's or agent's file reference D 1903-1 WO	**IMPORTANT NOTIFICATION**
International application No. PCT/EP98/08454	**International filing date** (day/month/year) 22 December 1998 (22.12.98)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
ASTRA AKTIEBOLAG Von Schuckmann, Alfred		
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
ASTRAZENECA AB S-151 85 Södertälje Sweden	SE	SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
Von Schuckmann, Alfred is now recorded as applicant and inventor for US only.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer C. Cupello
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

ASTRAZENECA AB
Intellectual Property, Patents
S-151 85 Södertälje
SUÈDE

Date of mailing (day/month/year)	
04 April 2000 (04.04.00)	
Applicant's or agent's file reference D 1903-1 WO	**IMPORTANT NOTIFICATION**
International application No. PCT/EP98/08454	**International filing date** (day/month/year) 22 December 1998 (22.12.98)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
ASTRA AKTIEBOLAG S-151 85 Södertälje Sweden	SE	SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
ASTRAZENECA AB S-151 85 Södertälje Sweden	SE	SE
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Marie-José Devillard
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 August 1999 (20.08.99)	
International application No. PCT/EP98/08454	**Applicant's or agent's file reference** D 1903-1 WO
International filing date (day/month/year) 22 December 1998 (22.12.98)	**Priority date** (day/month/year) 22 December 1997 (22.12.97)
Applicant VON SCHUCKMANN, Alfred et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

07 July 1999 (07.07.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Marie-José Devillard

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING DOCUMENT TRANSMITTED

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as designated Office

Date of mailing (day/month/year)
20 August 1999 (20.08.99)

International application No.
PCT/EP98/08454

International filing date (day/month/year)
22 December 1998 (22.12.98)

Applicant
ASTRA AKTIEBOLAG et al

The International Bureau transmits herewith the following documents and number thereof:

_____ cop(ies) of priority document(s) (Rule 17.2(a))

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Marie-José Devillard

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

ASTRA AKTIEBOLAG
Intellectual Property, Patents
S-151 85 Södertälje
SUÈDE

Date of mailing (day/month/year) 06 August 1999 (06.08.99)	
Applicant's or agent's file reference D 1903-1 WO	**IMPORTANT NOTIFICATION**
International application No. PCT/EP98/08454	International filing date (day/month/year) 22 December 1998 (22.12.98)
International publication date (day/month/year) 01 July 1999 (01.07.99)	Priority date (day/month/year) 22 December 1997 (22.12.97)
Applicant ASTRA AKTIEBOLAG et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
22 Dece 1997 (22.12.97)	197 57 207.3	DE	11 June 1999 (11.06.99)
22 Dece 1997 (22.12.97)	197 57 208.1	DE	NR

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Marie-José Devillard

Telephone No. (41-22) 338.83.38

N

16

PATENT COOPERATION TREATY

REC'D 29 FEB 2000

WIPO PCT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
N22731I/PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP98/08454	22/12/1998	22/12/1997
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant ASTRA AKTIEBOLAG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 33 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07/07/1999	24.02.00
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Lager, J Telephone No. +49 89 2399 2957

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP98/08454

I. Basis of the rep rt

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-25	as received on	24/09/1999	with letter of	22/09/1999

Claims, No.:

1-27	as received on	24/09/1999	with letter of	22/09/1999

Drawings, sheets:

1/24-18/24, 22/24-24/24	as originally filed			
19/24-21/24	as received on	24/09/1999	with letter of	22/09/1999

2. The amendments have resulted in the cancellation of:

☒ the description, pages: 25-32
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-10,16,20-24
Inventive step (IS)	Yes:	Claims	
	No:	Claims	11-15,17-19,25-27
Industrial applicability (IA)	Yes:	Claims	1-27
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Section V.

1. WO-A-97/40876 (D1) discloses a suction tube for administering powder containing medicament from a blister comprising a cavity sealed by a covering film (Claim 15). The suction tube S (figs. 12-14) comprises an elongate body which includes an inlet section at one end thereof, which includes an inlet and a cutting assembly 20. The cutting assembly comprises a cutting blade 28 which includes a cutting edge for making a cut in the covering film of a blister and a ram blade (page 22, lines 1-3) which includes a bearing surface for bearing on the covering film of the blister and pushing it into the cavity of the blister. The suction tube furthermore comprises an outlet section 17 at the other end thereof, which includes an outlet and provides a mouthpiece, and an inhalation channel 31 providing fluid communication between the inlet and the outlet through which powder in use is draw on inhalation by a user.

1.1 It follows that all features of claim 1 are disclosed in combination by D1.

1.2 D1 furthermore discloses the additional features of claims 2-10, 16, 20-24:
- Claims 2,3 page 21, lines 10-16;
- Claim 4 fig. 12-14;
- Claims 5,6 fig. 9;
- Claims 7,8 fig. 14 (corner of the blade 28 at gap 26);
- Claim 9 gap 26;
- Claim 10 fig 12-14;
- Claim 16 page 18, lines 11-17;
- Claim 20 fig. 14;
- Claim 21 page 24, lines 14-18;
- Claim 22 fig.11;
- Claim 23 sentence bridging pages 14,15, fig.11; and
- Claim 24 page 19, lines 18-27.

1.3 Claims 1-10, 16, 20-24 do not fulfil the requirements of Article 33(2) PCT.

2. Claims 11-15 define that the ram blade has at least one transverse opening. It appears however not that such opening provides an inventive step over the

embodiment disclosed in D1 figures 28-29.

2.1 Claims 11-15 do therefore not fulfil the requirements of Article 33(3) PCT.

3. Claims 17-19 define the geometric relation between the ram blades and the cutting blades. This geometry appears however not to provide an inventive step over the arrangement disclosed if figures 12-14 and 28-29 of D1.

3.1 Claims 17-19 do therefore not fulfil the requirements of Article 33(3) PCT.

4. Claims 25-27 define an inhaler with retention means for the suction tube. This however appears to be a technical equivalent to the provision disclosed in D1, see items 23-25.

4.1 Claims 25-27 do therefore not fulfil the requirements of Article 33(3) PCT.

Section VII.

1. Claim 1 is not presented in the two-part form based on D1, although this would be appropriate.

Section VIII.

1. Claims 20-21 are unclear in as far as they attempt to define the subject-matter by reference to features which do not form part of the subject-matter of the claims.

INHALATION DEVICE

The present invention relates to a suction tube for drawing powder containing medicament from a blister and an inhaler for administering dry powder by inhalation comprising the same.

It is known in the treatment of respiratory conditions, such as asthma, to provide certain medicaments in the form of a dry powder for inhalation. It is also known to provide individual doses of such powders in the blisters of a blister pack element.

WO-A-97/40876 discloses an inhaler for administering dry powder by inhalation which comprises a support unit for supporting a blister pack element having a plurality of blisters formed therein, with each blister containing a dose of powder containing medicament, and a suction tube configured so as to be insertable into a respective one of the blisters and through which a dose of powder is in use drawn on inhalation by a user. The support unit of this inhaler includes a chamber having a hinged lid for holding the suction tube when not in use.

It is an aim of the present invention to provide an improved suction tube for drawing powder containing medicament from a blister.

Accordingly, the present invention provides a suction tube for drawing powder containing medicament from a blister comprising a cavity sealed by a covering film, the suction tube comprising an elongate body which includes an inlet section at one end thereof, which inlet section includes an inlet and a cutting assembly comprising a cutting blade which includes a cutting edge for making a cut in the covering film of a blister and at least one ram blade which includes a bearing surface for bearing on the covering film of the blister and pushing the same into the cavity of the blister, an outlet section at the other end thereof, which outlet section includes an outlet and provides a mouthpiece, and an inhalation channel

providing fluid communication between the inlet and the outlet through which powder is in use drawn on inhalation by a user.

Preferably, the cutting edge of the cutting blade extends axially forward of the bearing surface of the at least one ram blade such that the covering film of a blister is at least partly cut by the cutting blade before the bearing surface of the at least one ram blade contacts the covering film of the blister.

More preferably, the cutting blade is disposed axially forward of the bearing surface of the at least one ram blade such that the covering film of a blister is cut by the cutting blade before the bearing surface of the at least one ram blade contacts the covering film of the blister.

Preferably, the cutting blade extends across the inlet.

Preferably, the inlet is substantially co-axial with the longitudinal axis of the body.

Preferably, the cutting blade is substantially co-axial with the longitudinal axis of the body.

Preferably, the cutting blade includes at least one cutting point.

More preferably, the cutting blade includes first and second sections which taper to a cutting point.

Preferably, the cutting blade includes at least one transverse opening axially rearward of the cutting edge thereof.

Preferably, the cutting blade is substantially planar.

Preferably, each ram blade includes at least one transverse opening.

In one embodiment the at least one transverse opening is axially rearward of the bearing surface of the ram blade.

In another embodiment the at least one transverse opening extends axially rearwardly from the bearing surface of the ram blade.

Preferably, the at least one transverse opening is asymmetrically located in the ram blade.

Preferably, the at least one ram blade is substantially planar.

Preferably, the inlet section includes supplementary air inlet openings into the inhalation channel at an axial position rearwardly adjacent the inlet.

Preferably, the cutting assembly includes first and second ram blades disposed on opposite sides of the cutting blade.

More preferably, each ram blade is disposed substantially the same radial distance from the cutting blade.

Preferably, the cutting assembly is configured such that the distance between the endmost points of the bearing surface of each of the ram blades is approximately the same distance as the distance between the endmost points of the effective cutting length of the cutting blade and the adjacent endmost points of the bearing surface of each of the ram blades.

Preferably, the axial position of the inlet is such that when the inlet section is located in a blister the inlet is located below the surface defining the opening of the cavity of the blister.

Preferably, the inlet section includes at least one surface which defines a shoulder which in use is located at the upper surface of the blister.

The present invention also extends to an inhaler for administering powder containing medicament by inhalation which comprises the above-described suction tube.

Preferably, the inhaler further comprises a support unit for supporting a blister pack element, wherein the support unit includes a wall member which includes a plurality of openings adjacent which the blister pack element is in use disposed such that a blister is located beneath each opening.

More preferably, the inlet section of the suction tube includes at least one surface which defines a shoulder that acts to limit the extent to which the suction tube can be inserted into the openings in the wall member.

Preferably, the openings in the wall member of the support unit each include at least one radial extension which each include a web member and the inlet section of the suction tube includes at least one resiliently-biased arm which supports a catch member and is configured to fit into the at least one radial extension of the openings in the wall member, with the catch member and the web member being configured to engage one another when the suction tube is inserted into one of the openings in the wall member.

More preferably, the openings in the wall member of the support unit each include first and second radial extensions and the inlet section of the suction tube includes first and second resiliently-biased arms.

Still more preferably, the first and second radial extensions of the openings in the wall member and the first and second arms of the inlet section of the suction tube are radially opposed.

Medicaments suitable for administration by the powder inhaler of the present invention are any which may be delivered by inhalation and include, for example, β2-adrenoreceptor

agonists, for example, salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators, for example, ipratropium bromide and the like; glucocorticosteroids, for example, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone and the like, and their pharmacologically acceptable esters and salts; antiallergic medicaments, for example, sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists; phospholipase-A2 (PLA2) inhibitors; platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments; tranquilisers; cardiac glycosides; hormones; antihypertensive medicaments; antidiabetic medicaments; antiparasitic medicaments; anticancer medicaments; sedatives; analgesic medicaments; antibiotics; antirheumatic medicaments; immunotherapies; antifungal medicaments; antihypotension medicaments; vaccines; antiviral medicaments; proteins; polypeptides and peptides, for example, peptide hormones and growth factors; polypeptide vaccines; enzymes; endorphines; lipoproteins and polypeptides involved in the blood coagulation cascade; vitamins; and others, for example, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

Figure 1 illustrates in use a perspective view of an inhaler in accordance with a preferred embodiment of the present invention;

Figure 2 illustrates an exploded perspective view of the inhaler of Figure 1;

AMENDED SHEET

Figure 3 illustrates a plan view of the inhaler of Figure 1, illustrated with the blister pack assembly separated from the support unit;

Figure 4 illustrates a side view of the inhaler of Figure 1, illustrated with the blister pack assembly separated from the support unit;

Figure 5 illustrates a plan view of the inhaler of Figure 1, illustrated with the blister pack assembly partially loaded into/unloaded from the support unit;

Figure 6 illustrates a side view of the inhaler of Figure 1, illustrated with the blister pack assembly partially loaded into/unloaded from the support unit;

Figure 7 illustrates a plan view of the inhaler of Figure 1, illustrated with the blister pack assembly loaded in the support unit;

Figure 8 illustrates a side view of the inhaler of Figure 1, illustrated with the blister pack assembly loaded in the support unit;

Figure 9 illustrates in enlarged scale a fragmentary vertical sectional view (along section I-I in Figure 1) of the inhaler of Figure 1;

Figure 10 illustrates in enlarged scale a fragmentary vertical sectional view (along section II-II in Figure 1) of the inhaler of Figure 1;

Figure 11 illustrates in enlarged a fragmentary vertical sectional view (along section III-III in Figure 1) of the inhaler of Figure 1;

Figure 12 illustrates a perspective view of the blister pack assembly of the inhaler of Figure 1;

Figure 13 illustrates in enlarged scale a fragmentary exploded perspective view of the blister pack unit of the blister pack assembly of Figure 12;

Figure 14 illustrates a fragmentary vertical sectional view (along section IV-IV in Figure 13) of the blister pack unit of Figure 13;

Figure 15 illustrates a fragmentary vertical sectional view (along section V-V in Figure 13) of the blister pack unit of Figure 13;

Figure 16(a) illustrates in enlarged scale a plan view of the blister pack element of the blister pack assembly of Figure 12;

Figure 16(b) illustrates an underneath plan view of the blister pack element of Figure 16(a);

Figure 16(c) illustrates a side view of the blister pack element of Figure 16(a);

Figure 16(d) illustrates one end view of the blister pack element of Figure 16(a);

Figure 16(e) illustrates the other end view of the blister pack element of Figure 16(a);

Figure 16(f) illustrates a vertical sectional view (along section VI-VI in Figure 16(a)) of the blister pack element of Figure 16(a);

Figure 16(g) illustrates a vertical sectional view (along section VII-VII in Figure 16(a)) of the blister pack element of Figure 16(a);

Figure 17(a) illustrates in enlarged scale a plan view of the attachment member of the blister pack unit of the blister pack assembly of Figure 12;

Figure 17(b) illustrates an underneath plan view of the attachment member of Figure 17(a);

Figure 17(c) illustrates an end view of the attachment member of Figure 17(a);

Figure 17(d) illustrates one side view of the attachment member of Figure 17(a);

Figure 17(e) illustrates the other side view of the attachment member of Figure 17(a);

Figure 18(a) illustrates in enlarged scale a first side view of the suction tube of the blister pack assembly of Figure 12;

Figure 18(b) illustrates a second, orthogonal side view of the suction tube of Figure 18(a);

Figure 18(c) illustrates a plan view of the suction tube of Figure 18(a);

Figure 18(d) illustrates an underneath plan view of the suction tube of Figure 18(a);

Figure 18(e) illustrates a fragmentary perspective view of the suction tube of Figure 18(a);

Figure 18(f) illustrates a vertical sectional view (along section VIII-VIII in Figure 18(a)) of the suction tube of Figure 18(a);

Figure 18(g) illustrates a vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a);

Figure 19(a) illustrates a plan view of the interconnecting member of the blister pack assembly of Figure 12;

Figure 19(b) illustrates a side view of the interconnecting member of Figure 19(a);

Figure 20(a) illustrates a plan view of the support unit of the inhaler of Figure 1, illustrated in the closed or storage configuration;

Figure 20(b) illustrates a side view of the support unit of Figure 20(a), illustrated in the closed or storage configuration;

Figure 20(c) illustrates one end view of the support unit of Figure 20(a), illustrated in the closed or storage configuration;

Figure 20(d) illustrates the other end view of the support unit of Figure 20(a), illustrated in the closed or storage configuration;

Figure 20(e) illustrates a plan view of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(f) illustrates a side view of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(g) illustrates in enlarged scale a fragmentary vertical sectional view (along section X-X in Figure 20(e)) of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(h) illustrates in enlarged scale a fragmentary vertical sectional view (along section XI-XI in Figure 20(e)) of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(i) illustrates in enlarged scale a vertical sectional view (along section XII-XII in Figure 20(e)) of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 21(a) illustrates a fragmentary vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a) when partly inserted into a blister;

Figure 21(b) illustrates a horizontal sectional view (along section XIII-XIII in Figure 21(a)) of the suction tube of Figure 18(a) when partly inserted into a blister;

Figure 22(a) illustrates a fragmentary vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a) when further inserted into a blister;

Figure 22(b) illustrates a horizontal sectional view (along section XIV-XIV in Figure 22(a)) of the suction tube of Figure 18(a) when further inserted into a blister;

Figure 23(a) illustrates a fragmentary vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a) when fully inserted into a blister;

Figure 23(b) illustrates a horizontal sectional view (along section XV-XV in Figure 23(a)) of the suction tube of Figure 18(a) when fully inserted into a blister;

Figure 24(a) illustrates a fragmentary perspective view of a first modified suction tube for the inhaler of Figure 1;

Figure 24(b) illustrates a vertical sectional view (along section XVI-XVI in Figure 24(a)) of the suction tube of Figure 24(a);

Figure 24(c) illustrates a vertical sectional view (along section XVII-XVII in Figure 24(a)) of the suction tube of Figure 24(a);

Figure 25(a) illustrates a fragmentary perspective view of a second modified suction tube for the inhaler of Figure 1;

Figure 25(b) illustrates a vertical sectional view (along section XVIII-XVIII in Figure 25(a)) of the suction tube of Figure 25(a);

Figure 25(c) illustrates a vertical sectional view (along section XIX-XIX in Figure 25(a)) of the suction tube of Figure 25(a);

Figure 26(a) illustrates a fragmentary perspective view of a third modified suction tube for the inhaler of Figure 1;

Figure 26(b) illustrates a vertical sectional view (along section XX-XX in Figure 26(a)) of the suction tube of Figure 26(a);

Figure 26(c) illustrates a vertical sectional view (along section XXI-XXI in Figure 26(a)) of the suction tube of Figure 26(a);

Figure 27(a) illustrates a fragmentary perspective view of a fourth modified suction tube for the inhaler of Figure 1;

Figure 27(b) illustrates a vertical sectional view (along section XXII-XXII in Figure 27(a)) of the suction tube of Figure 27(a);

Figure 27(c) illustrates a vertical sectional view (along section XXIII-XXIII in Figure 27(a)) of the suction tube of Figure 27(a);

Figure 28 illustrates a perspective view of a modified blister pack assembly for the inhaler of Figure 1;

Figure 29 illustrates in enlarged scale a fragmentary perspective view of the blister pack unit of the blister pack assembly of Figure 28;

Figure 30 illustrates in enlarged scale a fragmentary exploded perspective view of the blister pack unit of the blister pack assembly of Figure 28;

Figure 31 illustrates an exploded vertical sectional view (along section XXIV-XXIV in Figure 28) of the blister pack unit of the blister pack assembly of Figure 28; and

Figure 32 illustrates an exploded vertical sectional view (along section XXV-XXV in Figure 28) of the blister pack unit of the blister pack assembly of Figure 28.

The inhaler comprises a support unit 1 and a blister pack assembly 3 which in use is loaded thereinto.

The blister pack assembly 3 comprises a blister pack unit 5, a suction tube 7 and an interconnecting member 9 which connects the suction tube 7 to the blister pack unit 5 so as to prevent the suction tube 7 from being inadvertently separated from the blister pack unit 5.

The blister pack unit 5 comprises a blister pack element 11, in this embodiment of generally rectangular shape, which includes a plurality of blisters 12, each containing a dose of powder containing medicament, and an attachment member 13, to which the suction tube 7 is attachable, fixed to the blister pack element 11.

The blister pack element 11 comprises a substantially planar thin sheet 17 which includes a plurality of cavities 19, each defining a part of a respective blister 12, and first and second open channels 21, 23 which are separated by a web member 25 and extend along the longitudinal axis of the blister pack element 11. In this embodiment the sheet 17 is formed of a metal, such as aluminium, and the cavities 19 have a depth of about 4 mm and a diameter at the opening thereof of about 7.5 mm. In alternative embodiments the sheet 17 can be formed of a plastics material or a laminate of metal and plastics material. The first channel 21, in this embodiment a flattened U-shaped section, comprises first and second

opposed side wall members 21a, 21b and a bottom wall member 21c. The first channel 21 is of relatively short length and extends to one narrow end 22 of the blister pack element 11 so as to allow for a sliding fit thereto of mutually configured parts of the attachment member 13 as will be described in more detail hereinbelow. The bottom wall member 21c of the first channel 21 includes a downwardly-directed projection 29 which acts as a detent for fixing the attachment member 13 in position relative to the blister pack element 11 as again will be described in more detail hereinbelow. The second channel 23, in this embodiment of arcuate section, is elongate and includes first and second end wall members 23a, 23b. The web member 25 separating the first and second channels 21, 23 includes a groove 35 which extends across the width thereof and along the longitudinal axis of the blister pack element 11.

The blister pack element 11 further comprises a thin film 37, in this embodiment in two sections, which is attached to the substantially planar surface of the sheet 17 thereof so as to cover the openings of each of the cavities 19 and thereby enclose a dose of powder containing medicament in each blister 12. In this embodiment the film 37 is formed of a metal, such as aluminium, and is attached to the sheet 17 by one of welding or an adhesive.

The attachment member 13 comprises an elongate body 39 which is of substantially the same length as the one narrow end 22 of the blister pack element 11, first and second projections 41, 43 which extend from the mid-point of one side surface of the elongate body 39 and together define a U-shaped channel 45 for receiving the first channel 21 in the sheet 17 of the blister pack element 11 and first and second clips 47, 49 which extend from the respective ends of the other side surface of the elongate body 39 and are each separately configured to hold the suction tube 7 when not in use. In this embodiment the clips 47, 49 are configured such that when the suction tube 7 is attached to one of the clips 47, 49 the other of the clips 47, 49 acts as a guard to protect against damage of the suction tube 7. The first projection 41, in this embodiment of rectangular section, is of the same section as the upper, inner surface of the first channel 21 in the sheet 17 of the blister pack element 11 so as to be a close slideable fit therein and includes a groove 42 which extends along the

upper surface of the length thereof. The second projection 43, in this embodiment a flattened U-shaped section, comprises first and second opposed side wall members 43a, 43b and a bottom wall member 43c, with the first and second projections 41, 43 being configured such that the first and second side wall members 43a, 43b and the bottom wall member 43c of the second projection 43 are disposed opposite the side and bottom surfaces of the first projection 41. The upper, inner surface of the second projection 43 is of the same section as the outer, lower surface of the first channel 21 in the sheet 17 of the blister pack element 11 so as to be a close slideable fit thereabout, with the side wall members 43a, 43b of the second projection 43 being dimensioned so as to abut a lower surface of the sheet 17 of the blister pack element 11. The bottom wall member 43c of the second projection 43 includes an opening 51 therein for receiving the downwardly-directed projection 29 on the bottom wall member 21c of the first channel 21 in the sheet 17 of the blister pack element 11 when the attachment member 13 is fitted to the blister pack element 11 so as to fix the attachment member 13 in position relative to the blister pack element 11.

The suction tube 7, which will be described in further detail hereinbelow, comprises a generally elongate body 62 which includes an inlet section 63 at one end, which inlet section 63 includes a cutting assembly 64 for cutting the film 37 covering the cavities 19 of the blisters 12 in the blister pack element 11 and an inlet 65 through which powder containing medicament is in use drawn from a respective blister 12 on inhalation by a user, an outlet section 67 at the other end, which outlet section 67 includes an outlet 69 and provides a mouthpiece, and an inhalation channel 71 providing fluid communication between the inlet 65 and the outlet 69. The body 62 of the suction tube 7 includes at the outer surface thereof a plurality of ribs 73 for allowing a user to grip the same securely and a peripheral recess 75 for receiving a part of the interconnecting member 9 as will be described in more detail hereinbelow.

The interconnecting member 9 comprises a line 76 of a flexible material, preferably a plastics material, such as nylon, a clip 77 fixed to one end of the line 76 which is located in

the peripheral recess 75 in the outer surface of the body 62 of suction tube 7 so as to anchor the line 76 to the same and an element 79 fixed to the other end of the line 76 which is of larger dimension than the gauge of the line 76 and is in use located partly in the second channel 21 in the sheet 17 of the blister pack element 11. In this embodiment the clip 77 is part-circular and formed of a resilient material so as to be a snap-fit about the body 62 of the suction tube 7. With this configuration, the line 76 is anchored to the suction tube 7 but yet allows the suction tube 7 to rotate relative thereto. As will become apparent hereinbelow, the suction tube 7, in being rotatable relative to the clip 77 of the interconnecting member 9, has a much greater freedom of movement and thereby facilitates use.

The support unit 1 comprises a housing 81 which includes an opening 82 and defines a cavity 83 into which the blister pack element 11 of the blister pack assembly 3 is in use inserted and a cover member 84 for enclosing the blister pack assembly 3 when not in use.

The housing 81 comprises a first, upper wall member 85 which, in this embodiment, is substantially planar and of rectangular shape. The upper wall member 85 includes an upper, outer surface 85a and a lower, inner surface 85b adjacent which the blister pack element 11 of the blister pack assembly 3 is in use disposed. The upper wall member 85 also includes one free end 86 which defines a part of the opening 82 in the housing 81 through which the blister pack element 11 is in use inserted. The upper wall member 85 further includes a plurality of openings 87 which each overlie a respective one of the openings of the cavities 19 of the blisters 12 in the blister pack element 11 such that each of the blisters 12 can be emptied by inserting the suction tube 7 into a respective one of the openings 87. In this embodiment the openings 87 in the upper wall member 85 are each configured to have the same peripheral shape as the inlet section 63 of the suction tube 7 such that the openings 87 act as guides for guiding the inlet section 63 of the suction tube 7 into a respective blister 12 in the blister pack element 11. Each of the openings 87 includes first and second radial extensions 87a, 87b for receiving mutually configured parts on the inlet section 63 of the suction tube 7 as will be described hereinbelow. The radial

extensions 87a, 87b of the openings 87 each include a web member 89 which includes upper and lower surfaces 89a, 89b that are substantially parallel respectively to the upper and lower surfaces 85a, 85b of the upper wall member 85 of the housing 81. The web members 89 are of lesser thickness than the upper wall member 85 of the housing 81 and are disposed such that the upper and lower surfaces 89a, 89b thereof are stepped back respectively from the upper and lower surfaces 85a, 85b of the upper wall member 85. The upper wall member 85 of the housing 81 further includes an elongate slot 91 which extends from the one free end 86 thereof, in this embodiment along the longitudinal axis of the housing 81, and overlies the second channel 23 in the sheet 17 of the blister pack element 11 when fitted such that the line 76 of the interconnecting member 9 can be drawn thereinto and pass freely therealong. The elongate slot 91 includes a first, narrow section 91a at the upper surface 85a of the upper wall member 85 which is of a width smaller than the smallest dimension of the element 79 of the interconnecting member 9 so as to prevent that element 79 from passing therethrough and a second, wide section 91b at the lower surface 85b of the upper wall member 85 for receiving a part of the element 79 of the interconnecting member 9. In this embodiment the wide section 91b of the elongate slot 91 is arcuate in shape and flares outwardly to the lower surface 85b of the upper wall member 85. The upper wall member 85 of the housing 81 still further includes a plurality of elongate ribs 93 which extend downwardly from the lower surface 85b thereof parallel to the longitudinal axis of the housing 81. The ribs 93 are provided to space the upper surface of the blister pack element 11 from the lower surface 85a of the upper wall member 85 and thereby provide an air flow path to the blisters 12 in the blister pack element 11. Further, in this embodiment, one rib 93 is located on either side of the elongate slot 91 in the upper wall member 85 such that when the blister pack assembly 3 is fitted to the support unit 1 the second channel 23 in the sheet 17 of the blister pack element 11 and the wide section 91b of the elongate slot 91 define an enclosed track in which the element 79 of the interconnecting member 9 is captively held, with the limits of movement of the element 79 along the enclosed track being defined by the end wall members 23a, 23b of the second channel 23 in the sheet 17 of the blister pack element 11. It will be appreciated that this configuration, in not having the line 76 of the interconnecting member 9 fixed at one point,

is advantageous in that the line 76 of the interconnecting member 9 need only be as long as the distance between the furthestmost opening 87 and the elongate slot 91 in the upper wall member 85, which distance, in this embodiment, corresponds to approximately half of the width of the upper wall member 85. The upper wall member 85 of the housing 81 still further includes a recess 94 at that end thereof remote from the opening 82 in the housing 81. This recess 94 provides a means by which a user can push the blister pack element 11 a distance out of the housing 81 so as to facilitate withdrawal of the blister pack assembly 3.

The housing 81 further comprises a second, lower wall member 95, in this embodiment substantially planar and of rectangular shape, which is spaced in parallel relation to the upper wall member 85, first and second side wall members 97, 99 which extend between the sides of the upper and lower wall members 85, 95 and an end wall member 101 which extends between the ends of the upper and lower wall members 85, 95 remote from the opening 82 in the housing 81. In this embodiment the side wall members 97, 99 and the end wall member 101 each include a groove 97', 99', 101' into which the peripheral edge at the sides and the other end of the blister pack element 11 of the blister pack assembly 3 is in use located such that the blister pack element 11 is held in position adjacent the lower surface 85b of the upper wall member 85 of the housing 81.

The cover member 84 is hinged to the housing 81, in this embodiment at that end adjacent the opening 82 therein. In a preferred embodiment the housing 81 and the cover member 84 of the support unit 1 are integrally formed of a plastics material such that the hinged connection of the housing 81 and the cover member 84 is provided by a living hinge. The cover member 84 includes a catch member 102 at the free end thereof which is configured to engage the recess 94 in the upper wall member 85 of the housing 81 when the cover member 84 is closed and thereby hold the same closed.

As described hereinabove, the suction tube 7 includes an inlet section 63 which includes a cutting assembly 64 for cutting the film 37 covering the cavities 19 of the blisters 12 in the blister pack element 11.

The inlet section 63 of the suction tube 7 further includes first and second arms 105, 107 which extend forwardly, in the sense of insertion of the suction tube 7 into a blister 12, from respective sides thereof and are biased outwardly. The arms 105, 107 are each configured so as to be a sliding fit in the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81. In this way, the suction tube 7 can only be inserted into an opening 87 in the upper wall member 85 of the housing 81 in one of two orientations, and, as will become apparent hereinbelow, since the cutting assembly 64 has two-fold rotational symmetry, the suction tube 7 can never inadvertently be inserted into a blister 12 with another orientation which may cause the film 37 covering the respective blister 12 to be cut free. It will, of course, be appreciated that in any embodiment where the cutting assembly 64 of the suction tube 7 does not have such rotational symmetry the first and second arms 105, 107 at the inlet section 63 of the suction tube 7 and the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81 can be configured so as to permit the suction tube 7 to be inserted into the openings 87 in the upper wall member 85 of the housing 81 in only one orientation. Each of the first and second arms 105, 107 includes a catch member 109, 111 which is adapted to engage with the web members 89 in the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81. The catch members 109, 111 on the first and second arms 105, 107 each have a first surface 109a, 111a which has a forwardly-directed component and acts as a guiding surface and a second surface 109b, 111b which is substantially orthogonally directed to the longitudinal axis of the body 62 of the suction tube 7 and acts as a locking surface. In use, on fitting the suction tube 7 to the housing 81, the second, locking surfaces 109b, 111b of the catch members 109, 111 snap behind respective ones of the lower surfaces 89b of the web members 89 in the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81 so as to prevent the suction tube 7 from falling out of the respective opening 87 and thereby avoid the need for the user continuously to hold the suction tube 7 in position. It will be appreciated that the catch members 109, 111, in being a snap fit, provide the user with a clear indication that the suction tube 7 is correctly fitted to the housing 81 and hence inserted into a respective one

of the blisters 12 in the blister pack element 11. In this regard, the second, locking surfaces 109b, 111b of the catch members 109, 111 are configured so as to have only a small radial extent such as to allow the suction tube 7 to be removed from a respective one of the openings 87 in the upper wall member 85 of the housing 81 after use on the application of a light force.

The inlet section 63 of the suction tube 7 yet further includes a plurality of lugs 115 which extend radially therefrom and each include a lower surface 115' which defines a first shoulder that acts to limit the extent to which the suction tube 7 can be inserted into any of the openings 87 in the upper wall member 85 of the housing 81 and hence a respective blister 12 in the blister pack element 11. In this embodiment the lugs 115 are configured such that the shoulder defined by the lower surfaces 115' thereof abuts the upper surface 85a of the upper wall member 85 of the housing 81 on the required insertion of the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81. In this way, the suction tube 7 cannot be inserted too far into a blister 12 which could result in the cutting assembly 64 at the inlet section 63 of the suction tube 7 being forced inadvertently through the cavity 19 of any blister 12 on fitting the suction tube 7 to the housing 81.

The inlet section 63 of the suction tube 7 still further includes first and second axially-extending members 117, 119 which each include a lower surface 117', 119' that defines a second shoulder which is axially forward, in the sense of inserting the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, of the first shoulder defined by the lower surfaces 115' of the lugs 115. In this embodiment the first and second axially-extending members 117, 119 are configured such that the second shoulder defined by the lower surfaces 117', 119' thereof abuts the upper surface of the blister pack element 11 when the first shoulder defined by the lower surfaces 115' of the lugs 115 abuts the upper surface 85a of the upper wall member 85 of the housing 81.

The cutting assembly 64 of the inlet section 63 of the suction tube 7 comprises a cutting blade 127 and first and second ram blades 129, 131 disposed adjacent thereto.

The cutting blade 127 includes a cutting edge 133 which extends across and is located axially forward, in the sense of inserting the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, of the inlet 65 of the suction tube 7 such that, on insertion of the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, a cut is made in the film 37 covering the opening of the cavity 19 of the blister 12 therebeneath. In this embodiment the cutting edge 133 of the cutting blade 127 includes a cutting point 133'. The cutting blade 127, which in this embodiment is substantially planar, is co-axial with the longitudinal axis of the body 62 of the suction tube 7 and includes first and second flank sections 127a, 127b which taper to an axially-foremost cutting point 127c located on the longitudinal axis of the body 62 of the suction tube 7. In this embodiment the flank sections 127a, 127b of the cutting blade 127 enclose an angle of about 120 degrees. The cutting blade 127 has an effective cutting length approaching that of the diameter of the openings to the cavities 19 of the blisters 12 in the blister pack element 11 such that, on insertion of the suction tube 7 into a respective one of the openings 87 in the upper wall member 85 of the housing 81, the cutting blade 127 cuts the film 37 across the diameter of the opening to the cavity 19 of the respective blister 12. The cutting blade 127 further includes a transverse opening 134 located behind the cutting edge 133 thereof for providing an air flow path therethrough.

The first and second ram blades 129, 131, which in this embodiment are each substantially planar, are located to each side of the cutting blade 127, and, as will be described in more detail hereinbelow, are configured to bear on and push back the film 37 covering the cavity 19 of a respective one of the blisters 12 once cut by the cutting blade 127 and thereby open the blister 12. In this embodiment the first and second ram blades 129, 131 are disposed parallel to, and are the same radial distance from, the cutting blade 127. The first and second ram blades 129, 131 each include a lower, axially-forward surface 129', 131' which is located axially rearward of the axially foremost part of the cutting edge 133 of the cutting blade 127 such that the ram blades 129, 131 act on the film 37 only once at least

partly cut by the cutting blade 127. In this embodiment the bearing surface 129', 131' of each of the ram blades 129, 131 is substantially flat.

In a preferred embodiment the cutting assembly 64 of the suction tube 7 is configured such that the effective length of each of the bearing surfaces 129', 131' of the ram blades 129, 131, that is, the distance between the endmost points of the bearing surface 129', 131' of each of the ram blades 129, 131, is approximately the same distance as the distance between the adjacent endmost points of the bearing surfaces 129', 131' of the ram blades 129, 131 and the endmost points of the effective cutting length of the cutting blade 127. In this way, the film 37 covering the openings of the cavities 19 of any of the blisters 12 in the blister pack element 11 will be broken into flaps 136a-f of substantially equal size.

The action of the cutting assembly 64 of the suction tube 7 is clearly illustrated in Figures 21 to 23. In a first step, as illustrated in Figures 21(a) and 21(b), as the cutting assembly 64 is inserted into a blister 12 the cutting blade 127 makes a cut 135 across the diameter of the film 37 covering the opening of the cavity 19 of the blister 12. In a second step, as illustrated in Figures 22(a) and 22(b), as the cutting assembly 64 is inserted further into the blister 12 the bearing surfaces 129', 131' of the ram blades 129, 131 act on the film 37 and cause the film 37 to tear between adjacent endmost points of the bearing surface 129', 131' of the ram blades 129, 131 and the ends 135' of the cut 135 so as to form six flaps 136a-f. As mentioned hereinabove, in a preferred embodiment the cutting blade 127 and the ram blades 129, 131 are configured such that the flaps 136a-f are of substantially equal size. In a final step, as illustrated in Figures 23(a) and 23(b), the cutting assembly 64 is inserted further into the blister 12 until the second shoulder defined by the lower surfaces 117', 119' of the axially-directed members 117, 119 is at the upper surface of the blister pack element 11. In this position the suction tube 7 is inserted fully into the blister 12. In inserting the cutting assembly 64 further into blister 12 the ram blades 129, 131 cause the flaps 136a-f to be pushed to the wall of the cavity 19 of the blister 12 so as to provide a large opening in the film 37 covering the blister 12 which allows for the ready withdrawal of powder therefrom.

The inlet section 63 of the suction tube 7 still yet further includes first and second upper supplementary air inlet openings 137, 139 into the inhalation channel 71 of the suction tube 7. The first and second upper supplementary air inlet openings 137, 139 into the inhalation channel 71 provide supplementary air flow paths, which, on inhalation by a user, allow supplementary air to be drawn into the inhalation channel 71 and mix with the air and powder mixture drawn through the inhalation channel 71 from a blister 12 in the blister pack element 11. As will be appreciated, the provision of such supplementary air flow paths provides that for each unit volume of air inhaled the user inhales a reduced amount of powder containing medicament. Furthermore, the action of supplementary air mixing with an air and powder mixture drawn through the inhalation channel 71 induces turbulence and assists in the deagglomeration of that powder.

Figures 24 to 27 illustrate modified suction tubes 7 for the inhaler described hereinabove. Structurally, these modified suction tubes 7 are similar to the suction tube 7 of the inhaler described hereinabove and differ only in aspects of the inlet section 63, principally the cutting assembly 64. For this reason, and in order to avoid unnecessary duplication of description, only the structural differences of the suction tubes 7 will be described in detail and reference is made to the preceding description.

Figures 24(a) to (c) illustrate a first modified suction tube 7. This suction tube 7 differs from the first-mentioned suction tube 7 in two aspects. Firstly, the ram blades 129, 131 each include an opening 141, 143 which extends axially rearwardly from the bearing surface 129', 131' thereof for providing shorter air flow paths between the periphery of the cavity 19 of the blister 12 adjacent the ram blades 129, 131 and the inlet 65. Secondly, the inlet 65 to the inhalation channel 71 is located axially forward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. With this configuration, the inlet 65 to the

inhalation channel 71 is located within each blister 12 and thereby forces air to be drawn more deeply into the cavity 19 of the blister 12 on inhalation by a user.

Figures 25(a) to (c) illustrate a second modified suction tube 7. This suction tube 7 differs from the first-modified suction tube 7 in that the transverse opening 141, 143 in each of the ram blades 129, 131 is within the respective ram blade 129, 131.

Figures 26(a) to (c) illustrate a third modified suction tube 7. This suction tube 7 differs from the first-mentioned suction tube 7 in two aspects. Firstly, the inlet section 63 of the suction tube 7 further includes first and second lower supplementary air inlet openings 147, 149 into the inhalation channel 71 at a position adjacent, but in this embodiment axially rearward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. These first and second lower supplementary air inlet openings 147, 149 provide a supplementary air flow path into the inhalation channel 71 which promotes turbulent flow within the cavity 19 of the blister 12, which turbulence, as will be appreciated, assists in emptying the blister 12. Secondly, the inlet 65 to the inhalation channel 71 is located axially forward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. As described hereinabove in relation to the first-modified suction tube 7, with this configuration the inlet 65 to the inhalation channel 71 is located within each blister 12 and thereby forces air to be drawn more deeply into the cavity 19 of the blister 12 on inhalation by a user.

Figures 27(a) to (c) illustrate a fourth modified suction tube 7. This suction tube 7 differs from the first-mentioned suction tube 7 in two aspects. Firstly, the ram blades 129, 131 each include a transverse opening 141, 143 for providing shorter air flow paths between the periphery of the cavity 19 of the blister 12 adjacent the ram blades 129, 131 and the inlet 65. In this embodiment the openings 141, 143 in the ram blades 129, 131 are

asymmetrically located so as to promote turbulent flow in the cavities 19 of the blisters 12. Secondly, the inlet 65 to the inhalation channel 71 is located axially forward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. As again described hereinabove in relation to the first-modified suction tube 7, with this configuration the inlet 65 to the inhalation channel 71 is located within each blister 12 and thereby forces air to be drawn more deeply into the cavity 19 of the blister 12 on inhalation by a user.

Figures 28 to 32 illustrate a modified blister pack assembly 3 for the inhaler described hereinabove. Structurally, this modified blister pack assembly 3 is similar to the blister pack assembly 3 of the inhaler described hereinabove and differs only in aspects of the blister pack unit 5. For this reason, and in order to avoid unnecessary duplication of description, only the structural differences of the blister pack assemblies 3 will be described in detail and reference is made to the preceding description. This modified blister pack unit 5 differs principally from the blister pack unit 5 of the blister pack assembly 3 of the inhaler described hereinabove in that the sheet 17 of the blister pack element 11 includes a downwardly-depending peripheral skirt 151 and a plurality of downwardly-directed elongate ribs 153 which extend parallel to the longitudinal axis of the blister pack element 11. With this configuration the blister pack element 11 is configured to be a sliding fit in the cavity 83 of the housing 81 of the support unit 1, with the blister pack element 11 being self-supporting by the provision of the skirt 151 and the ribs 153. This modified blister pack unit 5 further differs from the blister pack unit 5 of the blister pack assembly 3 of the inhaler described hereinabove in the manner of the connection of the attachment member 13 in that the blister pack element 11 includes first and second projections 155, 157 at the one end 22 thereof to which the attachment member 13, which is also modified in not including the first and second projections 41, 43, is snap fitted. This modified blister pack unit 5 yet further differs from the blister pack unit 5 of the blister pack assembly 3 of the inhaler described hereinabove in further including moisture-permeable chambers 159 which contain desiccant disposed to the lower surface of the sheet

17 of the blister pack element 11 at at least some of the junctions between the cavities 19 defining the blisters 12 and in including a thin film 161 covering the lower surface thereof.

In use, a user takes the inhaler in one hand and opens up the cover member 84 of the support unit 1 so as to expose the suction tube 7 and the upper wall member 85 of the housing 81. The user then unclips the suction tube 7 from the attachment member 13 and inserts the inlet section 63 of the suction tube 7 through one of the openings 87 in the upper wall member 85 of the housing 81 and into an unused blister 12. In inserting the inlet section 63 of the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, the user has first to align the arms 105, 107 thereon with the radial extensions 87a, 87b of the openings 87 and then push in the suction tube 7 until the first shoulder defined by the lower surfaces 115' of the lugs 115 abuts the upper surface 85a of the upper wall member 85 and the catches 109, 111 on the arms 105, 107 snap behind the web members 89 in the radial extensions 87a, 87b of the openings 87. The user then takes the mouthpiece provided by the outlet section 67 of the suction tube 7 in his/her lips and inhales so as to withdraw the dose of powder containing powder from the blister 12 and deliver the same into the lungs. After inhalation, the user withdraws the suction tube 7 from the opening 87 in the upper wall member 85 of the housing 81, which will require the application of a light force to overcome the action of the catches 109, 111 on the arms 105, 107 of the suction tube 7, and then clips the suction tube 7 back to the attachment member 13. This pattern of use can be repeated until all of the blisters 12 in the blister pack element 11 of the blister pack assembly 3 have been used. When all of the blisters 12 in the blister pack element 11 have been used, the user withdraws the blister pack assembly 3 form the support unit 1 and replaces that used blister pack assembly 3 with a new blister pack assembly 3.

Finally, it will be understood by a person skilled in the art that the present invention is not limited to the described embodiments but can be modified in many different ways without departing from the scope of the invention as defined by the appended claims.

CLAIMS

1. A suction tube for drawing powder containing medicament from a blister (12) comprising a cavity (19) sealed by a covering film (37), the suction tube comprising an elongate body (62) which includes an inlet section (63) at one end thereof, which inlet section (63) includes an inlet (65) and a cutting assembly (64) comprising a cutting blade (127) which includes a cutting edge (133) for making a cut in the covering film (37) of a blister (12) and at least one ram blade (129, 131) which includes a bearing surface (129', 131') for bearing on the covering film (37) of the blister (12) and pushing the same into the cavity (19) of the blister (12), an outlet section (67) at the other end thereof, which outlet section (67) includes an outlet (69) and provides a mouthpiece, and an inhalation channel (71) providing fluid communication between the inlet (65) and the outlet (69) through which powder is in use drawn on inhalation by a user.

2. The suction tube according to claim 1, wherein the cutting edge (133) of the cutting blade (127) extends axially forward of the bearing surface (129', 131') of the at least one ram blade (129, 131) such that the covering film (37) of a blister (12) is at least partly cut by the cutting blade (127) before the bearing surface (129', 131') of the at least one ram blade (129, 131) contacts the covering film (37) of the blister (12).

3. The suction tube according to claim 2, wherein the cutting blade (127) is disposed axially forward of the bearing surface (129', 131') of the at least one ram blade (129, 131) such that the covering film (37) of a blister (12) is cut by the cutting blade (127) before the bearing surface (129', 131') of the at least one ram blade (129, 131) contacts the covering film (37) of the blister (12).

4. The suction tube according to any of claims 1 to 3, wherein the cutting blade (127) extends across the inlet (65).

5. The suction tube according to any of claims 1 to 4, wherein the inlet (65) is substantially co-axial with the longitudinal axis of the body (62).

6. The suction tube according to any of claims 1 to 5, wherein the cutting blade (127) is substantially co-axial with the longitudinal axis of the body (62).

7. The suction tube according to any of claims 1 to 6, wherein the cutting blade (127) includes at least one cutting point (127c).

8. The suction tube according to claim 7, wherein the cutting blade (127) includes first and second sections (127a, 127b) which taper to a cutting point (127c).

9. The suction tube according to any of claims 1 to 8, wherein the cutting blade (127) includes at least one transverse opening (134) axially rearward of the cutting edge (133) thereof.

10. The suction tube according to any of claims 1 to 9, wherein the cutting blade (127) is substantially planar.

11. The suction tube according to any of claims 1 to 10, wherein each ram blade (129, 131) includes at least one transverse opening (141, 143).

12. The suction tube according to claim 11, wherein the at least one transverse opening (141, 143) is axially rearward of the bearing surface (129', 131') of the ram blade (129, 131).

13. The suction tube according to claim 11, wherein the at least one transverse opening (141, 143) extends axially rearwardly from the bearing surface (129', 131') of the ram blade (129, 131).

14. The suction tube according to any of claims 11 to 13, wherein the at least one transverse opening (141, 143) is asymmetrically located in the ram blade (129, 131).

15. The suction tube according to claim 14, wherein the at least one ram blade (129, 131) is substantially planar.

16. The suction tube according to any of claims 1 to 15, wherein the inlet section (63) includes supplementary air inlet openings (147, 149) into the inhalation channel (71) at an axial position rearwardly adjacent the inlet (65).

17. The suction tube according to any of claims 1 to 16, wherein the cutting assembly (64) includes first and second ram blades (129, 131) disposed on opposite sides of the cutting blade (127).

18. The suction tube according to claim 17, wherein each ram blade (129, 131) is disposed substantially the same radial distance from the cutting blade (127).

19. The suction tube according to claim 17 or 18, wherein the cutting assembly (64) is configured such that the distance between the endmost points of the bearing surface (129', 131') of each of the ram blades (129, 131) is approximately the same distance as the distance between the endmost points of the effective cutting length of the cutting blade (127) and the adjacent endmost points of the bearing surface (129', 131') of each of the ram blades (129, 131).

20. The suction tube according to any of claims 1 to 19, wherein the axial position of the inlet (65) is such that when the inlet section (63) is located in a blister (12) the inlet (65) is located below the surface defining the opening of the cavity (19) of the blister (12).

21. The suction tube according to any of claims 1 to 20, wherein the inlet section (63) includes at least one surface (117', 119') which defines a shoulder which in use is located at the upper surface of the blister (12).

22. An inhaler for administering dry powder by inhalation, comprising the suction tube (7) according to any of claims 1 to 21.

23. The inhaler according to claim 22, further comprising a support unit (1) for supporting a blister pack element (11), wherein the support unit (1) includes a wall member (85) which includes a plurality of openings (87) adjacent which the blister pack element (11) is in use disposed such that a blister (12) is located beneath each opening (87).

24. The inhaler according to claim 23, wherein the inlet section (63) of the suction tube (7) includes at least one surface (115') which defines a shoulder that acts to limit the extent to which the suction tube (7) can be inserted into the openings (87) in the wall member (85).

25. The inhaler according to claim 23 or 24, wherein the openings (87) in the wall member (85) of the support unit (1) each include at least one radial extension (87a, 87b) which each include a web member (89) and the inlet section (63) of the suction tube (7) includes at least one resiliently-biased arm (105, 107) which supports a catch member (109, 111) and is configured to fit into the at least one radial extension (87a, 87b) of the openings (87) in the wall member (85), with the catch member (109, 111) and the web member (89) being configured to engage one another when the suction tube (7) is inserted into one of the openings (87) in the wall member (85).

26. The inhaler according to claim 25, wherein the openings (87) in the wall member (85) of the support unit (1) each include first and second radial extensions (87a, 87b) and the inlet section (63) of the suction tube (7) includes first and second resiliently-biased arms (105, 107).

27. The inhaler according to claim 26, wherein the first and second radial extensions (87a, 87b) of the openings (87) in the wall member (85) and the first and second arms (105, 107) of the inlet section (63) of the suction tube (7) are radially opposed.

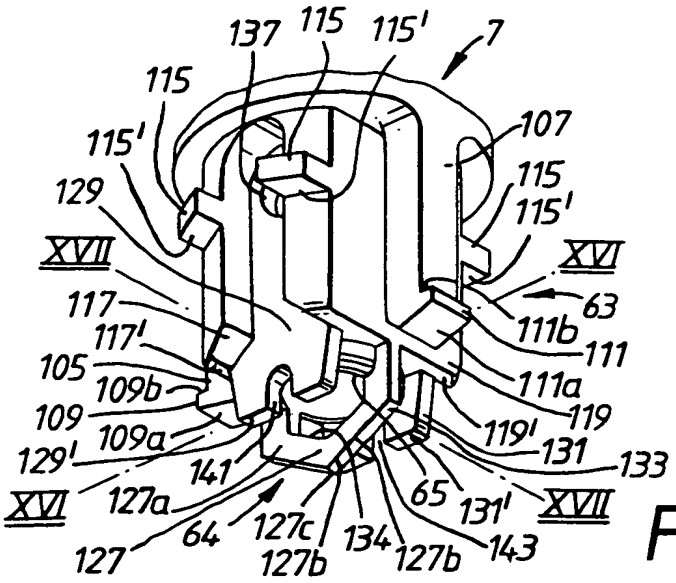


Fig.24(a)

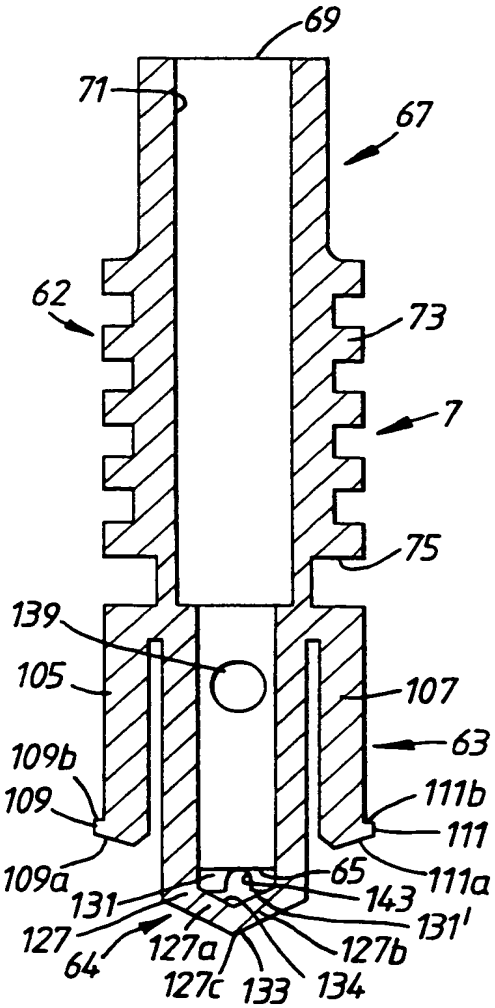


Fig.24(b)

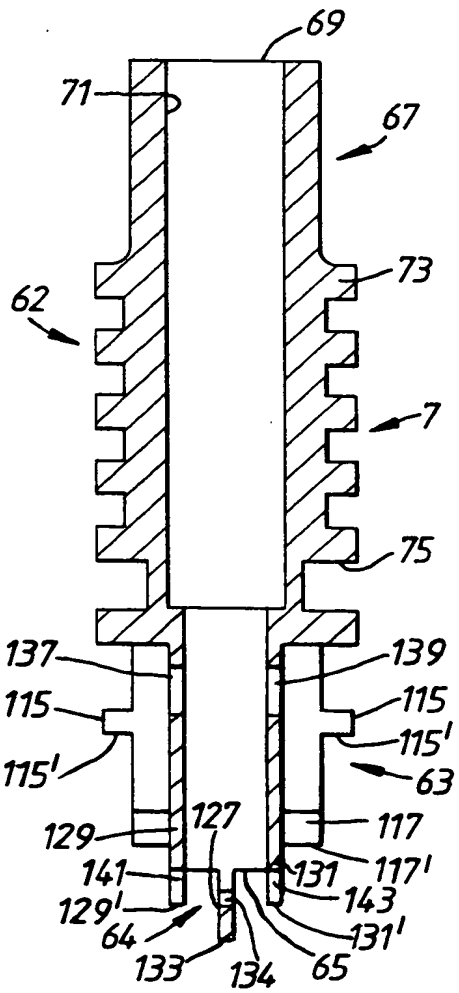


Fig.24(c)

AMENDED SHEET

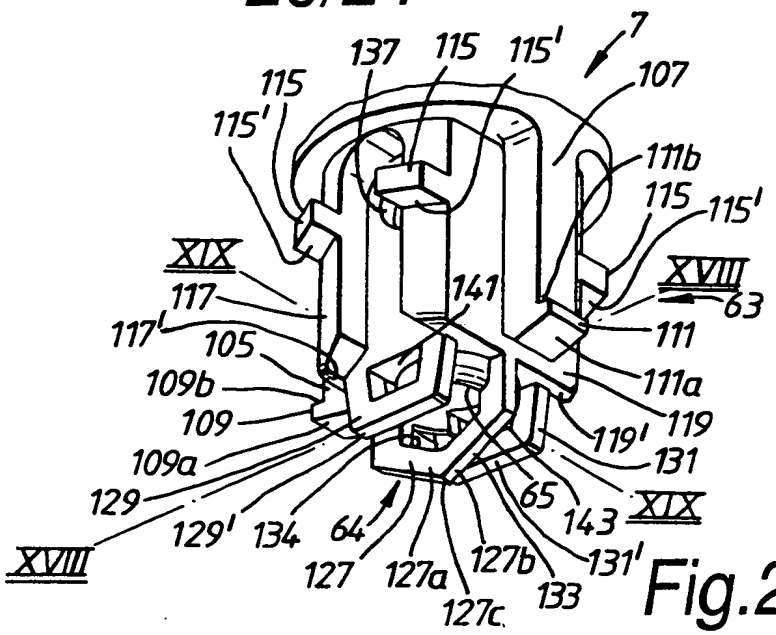


Fig.25(a)

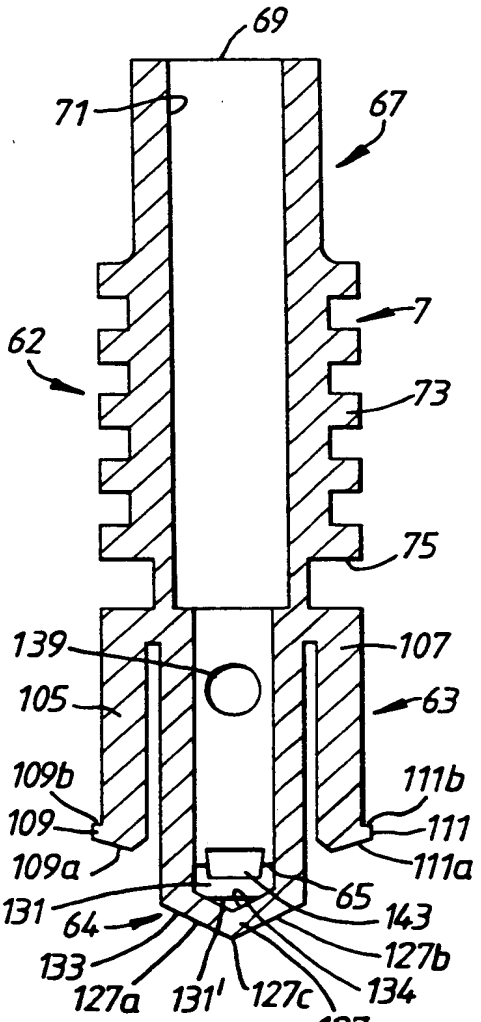


Fig.25(b)

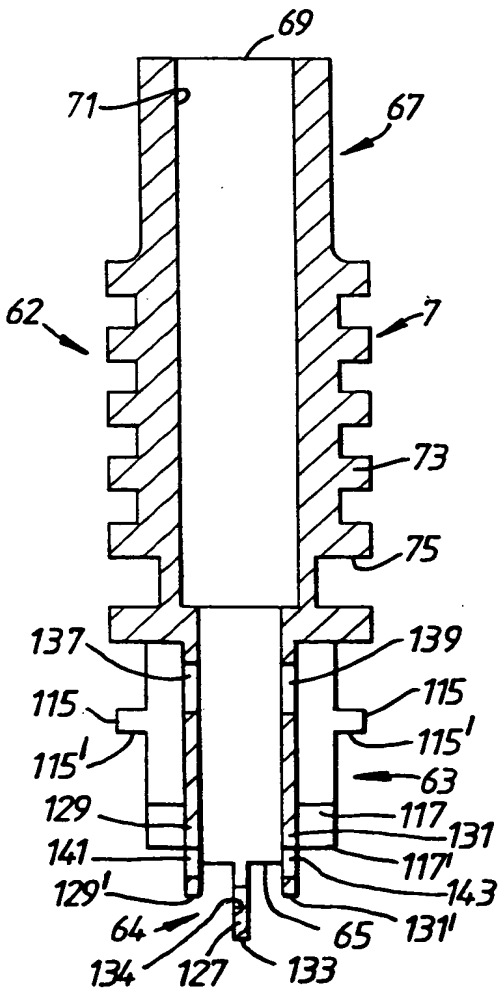


Fig.25(c)

AMENDED SHEET

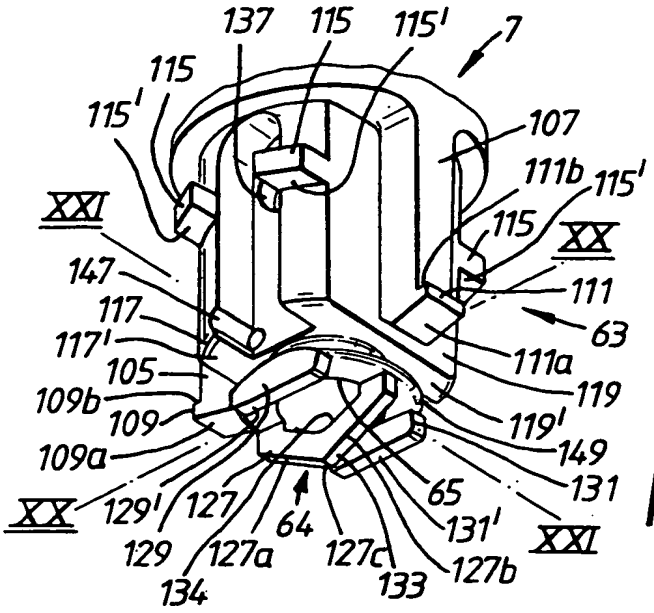


Fig.26(a)

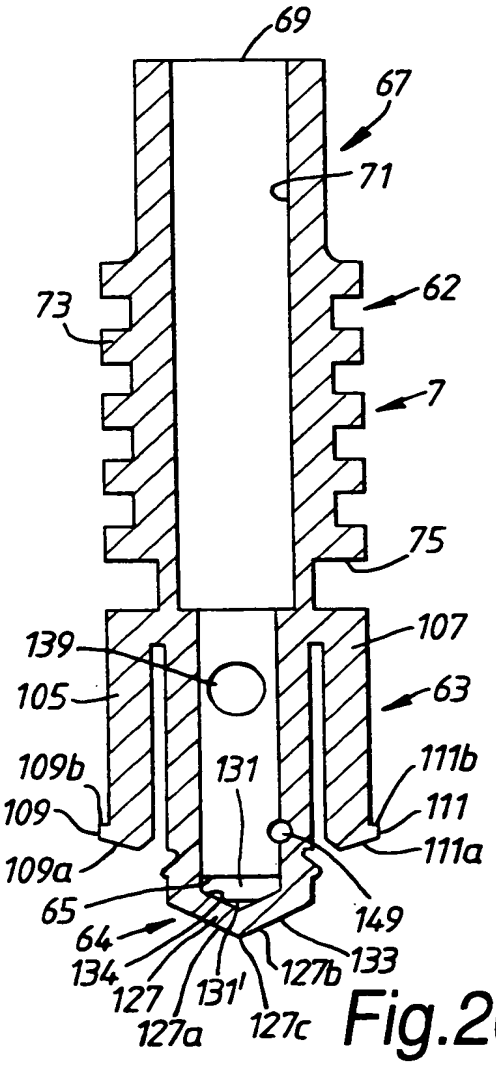


Fig.26(b)

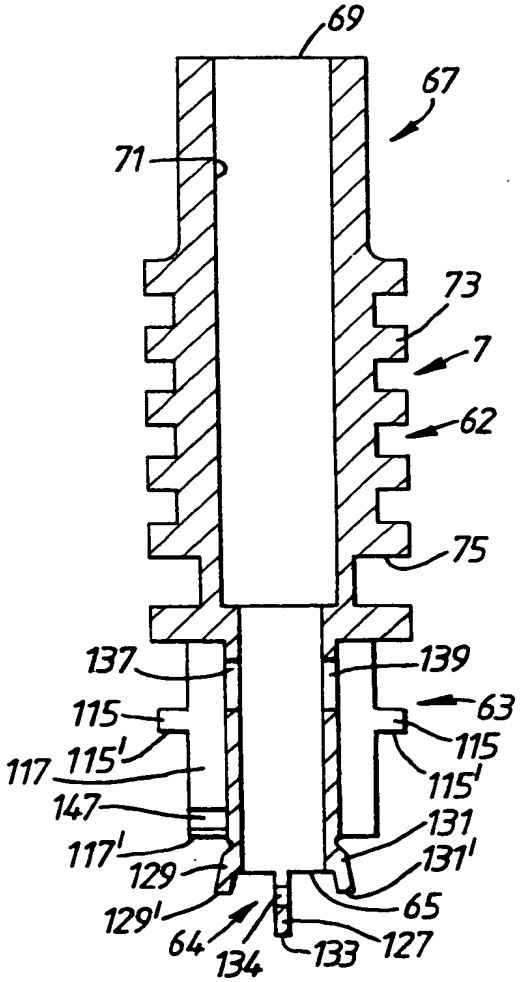


Fig.26(c)

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 15/00 — A1

(11) International Publication Number: **WO 99/32180**

(43) International Publication Date: 1 July 1999 (01.07.99)

(21) International Application Number: PCT/EP98/08454

(22) International Filing Date: 22 December 1998 (22.12.98)

(30) Priority Data:
197 57 207.3 22 December 1997 (22.12.97) DE
197 57 208.1 22 December 1997 (22.12.97) DE

(71) Applicant *(for all designated States except US)*: ASTRA AKTIEBOLAG [SE/SE]; S–151 85 Södertälje (SE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: VON SCHUCKMANN, Alfred [DE/DE]; Winnekendonker Strasse 52, D–47627 Kevelaer (DE). ULLBRAND, Björn [SE/SE]; Astra Draco AB, P.O. Box 24, S–221 00 Lund (SE). SELMER, Anders [SE/SE]; Astra Draco AB, P.O. Box 24, S–221 00 Lund (SE).

(74) Agent: ASTRA AKTIEBOLAG; Intellectual Property, Patents, S–151 85 Södertälje (SE).

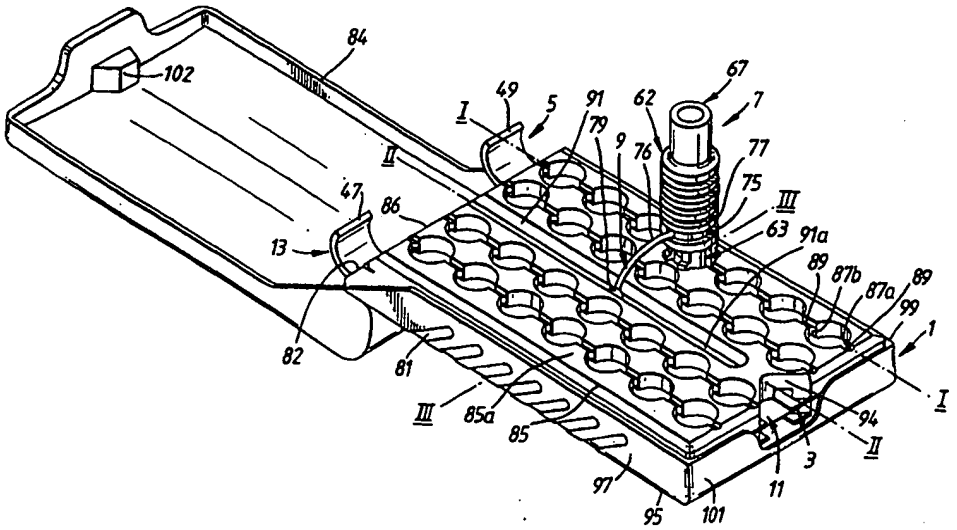
(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: INHALATION DEVICE



(57) Abstract

A suction tube for administering powder containing medicament from a blister (12) comprising a cavity (19) sealed by a covering film (37), the suction tube comprising an elongate body (62) which includes an inlet section (63) at one end thereof, which inlet section (63) includes an inlet (65) and a cutting assembly (64) comprising a cutting blade (127) which includes a cutting edge (133) for making a cut in the covering film (37) of a blister (12) and at least one ram blade (129, 131) which includes a bearing surface (129', 131') for bearing on the covering film (37) of the blister (12) and pushing the same into the cavity (19) of the blister (12), an outlet section (67) at the other end thereof, which outlet section (67) includes an outlet (69) and provides a mouthpiece, and an inhalation channel (71) providing fluid communication between the inlet (65) and the outlet (69) through which powder is in use drawn on inhalation by a user.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

INHALATION DEVICE

The present invention relates to an inhaler, more particularly an inhaler for administering dry powder by inhalation, a blister pack assembly for an inhaler and a suction tube for an inhaler.

It is known in the treatment of respiratory conditions, such as asthma, to provide certain medicaments in the form of a dry powder for inhalation. It is also known to provide individual doses of such powders in the blisters of a blister pack.

WO-A-97/40876 discloses an inhaler for administering dry powder which comprises a support unit for supporting a blister pack element having a plurality of blisters formed therein, with each blister containing a dose of powder containing medicament, and a suction tube configured so as to be insertable into a respective one of the blisters and through which a dose of powder is in use drawn on inhalation by a user. The support unit includes a chamber having a hinged lid for holding the suction tube when not in use.

It is an aim of the present invention to provide such an inhaler and related components which are of improved construction so as to facilitate ease of operation by a user.

The present invention provides a blister pack assembly for an inhaler for administering powder containing medicament by inhalation, comprising: a suction tube through which powder is in use drawn on inhalation by a user; and a blister pack unit comprising a blister pack element which includes a plurality of blisters, each containing a dose of powder containing medicament, and an attachment member disposed to one side of the blister pack element to which the suction tube is attachable when not in use.

Preferably, the attachment member includes at least one attachment element which is configured resiliently to hold the suction tube.

More preferably, the attachment member includes first and second attachment elements which are configured such that when the suction tube is attached to one of the first and second attachment elements the other of the first and second attachment elements acts as a guard to protect part of the suction tube.

Preferably, each attachment element is a resilient clip.

Preferably, the blister pack assembly further comprises an interconnecting member for connecting the suction tube to the blister pack unit.

Preferably, the interconnecting member is movably coupled to the suction tube.

More preferably, the interconnecting member includes a clip to which the suction tube is rotatably coupled.

Preferably, the interconnecting member includes an element which is slideably disposed to the blister pack unit.

In one embodiment the blister pack unit includes an elongate track in which the element of the interconnecting member is captively slideably disposed.

Preferably, the elongate track extends along the longitudinal axis of the blister pack unit.

In another embodiment the blister pack unit includes an elongate channel and the element of the interconnecting member in use is slideably disposed in the channel.

Preferably, the elongate channel extends along the longitudinal axis of the blister pack unit.

Preferably, the blister pack unit includes at least one moisture permeable chamber which contains a desiccant.

More preferably, the at least one moisture permeable chamber is disposed between cavities of the blisters.

Preferably, the suction tube comprises an elongate body which includes an inlet section at one end thereof, which inlet section includes an inlet and a cutting assembly comprising a cutting blade which includes a cutting edge for making a cut in the covering film of a blister and at least one ram blade which includes a bearing surface for bearing on the covering film of the blister and pushing the same into the cavity of the blister, an outlet section at the other end thereof, which outlet section includes an outlet and provides a mouthpiece, and an inhalation channel providing fluid communication between the inlet and the outlet through which powder is in use drawn on inhalation by a user.

Preferably, each ram blade includes at least one transverse opening.

In one embodiment the at least one transverse opening is axially rearward of the bearing surface of the ram blade.

In another embodiment the at least one transverse opening extends axially rearwardly from the bearing surface of the ram blade.

Preferably, the at least one transverse opening is asymmetrically located in the ram blade.

Preferably, the at least one ram blade is substantially planar.

Preferably, the inlet section of the suction tube includes supplementary air inlet openings into the inhalation channel at an axial position rearwardly adjacent the inlet.

Preferably, the cutting assembly of the suction tube includes first and second ram blades disposed on opposite sides of the cutting blade.

More preferably, each ram blade is disposed substantially the same radial distance from the cutting blade.

Preferably, the cutting assembly of the suction tube is configured such that the distance between the endmost points of the bearing surface of each of the ram blades is approximately the same distance as the distance between the endmost points of the effective cutting length of the cutting blade and the adjacent endmost points of the bearing surface of each of the ram blades.

Preferably, the axial position of the inlet is such that when the inlet section is located in a blister the inlet is located below the surface defining the opening of the cavity of the blister.

The present invention also extends to an inhaler for administering powder containing medicament by inhalation which comprises the above-described blister pack assembly.

Preferably, the inhaler further comprises a support unit for supporting the blister pack assembly.

More preferably, the support unit includes a wall member which includes a plurality of openings adjacent which the blister pack element of the blister pack assembly is in use disposed such that a blister is located beneath each opening.

Preferably, the support unit includes an elongate slot which together with the elongate channel in the blister pack unit defines an elongate track in which the element of the interconnecting member is captively slideably disposed.

More preferably, the elongate slot extends along the longitudinal axis of the support unit.

Preferably, the elongate slot includes a narrow section through which the element of the interconnecting member cannot pass.

Preferably, the elongate slot is located in the wall member of the support unit.

The present invention also provides an inhaler for administering powder containing medicament by inhalation, comprising: a suction tube through which powder is in use drawn on inhalation by a user; a support unit for supporting a blister pack element which includes a plurality of blisters, each containing a dose of powder containing medicament: and an interconnecting member connecting the suction tube to the support unit, wherein the interconnecting member includes an element which is slideably disposed to the support unit.

Preferably, the support unit includes an elongate track in which the element of the interconnecting member is captively slideably disposed.

Preferably, the interconnecting member is movably coupled to the suction tube.

More preferably, the interconnecting member includes a clip to which the suction tube is rotatably coupled.

Preferably, the suction tube comprises an elongate body which includes an inlet section at one end thereof, which inlet section includes an inlet and a cutting assembly comprising a cutting blade which includes a cutting edge for making a cut in the covering film of a blister and at least one ram blade which includes a bearing surface for bearing on the covering film of the blister and pushing the same into the cavity of the blister, an outlet section at the other end thereof, which outlet section includes an outlet and provides a mouthpiece, and an inhalation channel providing fluid communication between the inlet and the outlet through which powder is in use drawn on inhalation by a user.

The present invention further provides a blister pack assembly for an inhaler for administering powder containing medicament by inhalation, comprising: a suction tube through which powder is in use drawn on inhalation by a user; a blister pack element which includes a plurality of blisters, each containing a dose of powder containing medicament; and an interconnecting member connecting the suction tube to the blister pack element, wherein the interconnecting member includes an element which is slideably disposed to the blister pack element.

Preferably, the interconnecting member is movably coupled to the suction tube.

More preferably, the interconnecting member includes a clip to which the suction tube is rotatably coupled.

In one embodiment the blister pack element includes an elongate track in which the element of the interconnecting member is captively slideably disposed.

Preferably, the elongate track extends along the longitudinal axis of the blister pack element.

In another embodiment the blister pack element includes an elongate channel and the element of the interconnecting member in use is slideably disposed in the channel.

Preferably, the elongate channel extends along the longitudinal axis of the blister pack element.

Preferably, the blister pack element includes at least one moisture permeable chamber which contains a desiccant.

More preferably, the at least one moisture permeable chamber is disposed between cavities of the blisters.

Preferably, the suction tube comprises an elongate body which includes an inlet section at one end thereof, which inlet section includes an inlet and a cutting assembly comprising a cutting blade which includes a cutting edge for making a cut in the covering film of a blister and at least one ram blade which includes a bearing surface for bearing on the covering film of the blister and pushing the same into the cavity of the blister, an outlet section at the other end thereof, which outlet section includes an outlet and provides a mouthpiece, and an inhalation channel providing fluid communication between the inlet and the outlet through which powder is in use drawn on inhalation by a user.

The present invention also extends to an inhaler for administering powder containing medicament by inhalation which comprises the above-described blister pack assembly.

Preferably, the inhaler further comprises a support unit for supporting the blister pack assembly.

More preferably, the support unit includes a wall member which includes a plurality of openings adjacent which the blister pack element of the blister pack assembly is in use disposed such that a blister is located beneath each opening.

Preferably, the support unit includes an elongate slot which together with the elongate channel in the blister pack element defines an elongate track in which the element of the interconnecting member is captively slideably disposed.

More preferably, the elongate slot extends along the longitudinal axis of the support unit.

Preferably, the elongate slot includes a narrow section through which the element of the interconnecting member cannot pass.

The present invention yet further provides a suction tube for administering powder containing medicament from a blister comprising a cavity sealed by a covering film, the suction tube comprising an elongate body which includes an inlet section at one end thereof, which inlet section includes an inlet and a cutting assembly comprising a cutting blade which includes a cutting edge for making a cut in the covering film of a blister and at least one ram blade which includes a bearing surface for bearing on the covering film of the blister and pushing the same into the cavity of the blister, an outlet section at the other end thereof, which outlet section includes an outlet and provides a mouthpiece, and an inhalation channel providing fluid communication between the inlet and the outlet through which powder is in use drawn on inhalation by a user.

Preferably, the cutting edge of the cutting blade extends axially forward of the bearing surface of the at least one ram blade such that the covering film of a blister is at least partly cut by the cutting blade before the bearing surface of the at least one ram blade contacts the covering film of the blister.

More preferably, the cutting blade is disposed axially forward of the bearing surface of the at least one ram blade such that the covering film of a blister is cut by the cutting blade before the bearing surface of the at least one ram blade contacts the covering film of the blister.

Preferably, the cutting blade extends across the inlet.

Preferably, the inlet is substantially co-axial with the longitudinal axis of the body.

Preferably, the cutting blade is substantially co-axial with the longitudinal axis of the body.

Preferably, the cutting blade includes at least one cutting point.

More preferably, the cutting blade includes first and second sections which taper to a cutting point.

Preferably, the cutting blade includes at least one transverse opening axially rearward of the cutting edge thereof.

Preferably, the cutting blade is substantially planar.

Preferably, each ram blade includes at least one transverse opening.

In one embodiment the at least one transverse opening is axially rearward of the bearing surface of the ram blade.

In another embodiment the at least one transverse opening extends axially rearwardly from the bearing surface of the ram blade.

Preferably, the at least one transverse opening is asymmetrically located in the ram blade.

Preferably, the at least one ram blade is substantially planar.

Preferably, the inlet section includes supplementary air inlet openings into the inhalation channel at an axial position rearwardly adjacent the inlet.

Preferably, the cutting assembly includes first and second ram blades disposed on opposite sides of the cutting blade.

More preferably, each ram blade is disposed substantially the same radial distance from the cutting blade.

Preferably, the cutting assembly is configured such that the distance between the endmost points of the bearing surface of each of the ram blades is approximately the same distance as the distance between the endmost points of the effective cutting length of the cutting blade and the adjacent endmost points of the bearing surface of each of the ram blades.

Preferably, the axial position of the inlet is such that when the inlet section is located in a blister the inlet is located below the surface defining the opening of the cavity of the blister.

Preferably, the inlet section includes at least one surface which defines a shoulder which in use is located at the upper surface of the blister.

The present invention also extends to an inhaler for administering powder containing medicament by inhalation which comprises the above-described suction tube.

Preferably, the inhaler further comprises a support unit for supporting a blister pack element, wherein the support unit includes a wall member which includes a plurality of openings adjacent which the blister pack element is in use disposed such that a blister is located beneath each opening.

More preferably, the inlet section of the suction tube includes at least one surface which defines a shoulder that acts to limit the extent to which the suction tube can be inserted into the openings in the wall member.

Preferably, the openings in the wall member of the support unit each include at least one radial extension which each include a web member and the inlet section of the suction tube includes at least one resiliently-biased arm which supports a catch member and is configured to fit into the at least one radial extension of the openings in the wall member, with the catch member and the web member being configured to engage one another when the suction tube is inserted into one of the openings in the wall member.

More preferably, the openings in the wall member of the support unit each include first and second radial extensions and the inlet section of the suction tube includes first and second resiliently-biased arms.

Still more preferably, the first and second radial extensions of the openings in the wall member and the first and second arms of the inlet section of the suction tube are radially opposed.

Preferably, the slot is located in the wall member of the support unit.

Medicaments suitable for administration by the powder inhaler of the present invention are any which may be delivered by inhalation and include for example β2-adrenoreceptor agonists, for example, salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their pharmacologically acceptable esters and salts; anticholinergic bronchodilators, for example, ipratropium bromide and the like; glucocorticosteroids, for example, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone and the like, and their pharmacologically acceptable esters and salts; antiallergic medicaments, for example, sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists; phospholipase-A2 (PLA2) inhibitors; platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments; tranquilisers; cardiac glycosides; hormones; antihypertensive medicaments; antidiabetic medicaments; antiparasitic medicaments; anticancer medicaments; sedatives; analgesic medicaments; antibiotics; antirheumatic medicaments; immunotherapies; antifungal medicaments; antihypotension medicaments; vaccines; antiviral medicaments; proteins; polypeptides and peptides, for

example, peptide hormones and growth factors; polypeptide vaccines; enzymes; endorphines; lipoproteins and polypeptides involved in the blood coagulation cascade; vitamins; and others, for example, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

Figure 1 illustrates in use a perspective view of an inhaler in accordance with a preferred embodiment of the present invention;

Figure 2 illustrates an exploded perspective view of the inhaler of Figure 1;

Figure 3 illustrates a plan view of the inhaler of Figure 1, illustrated with the blister pack assembly separated from the support unit;

Figure 4 illustrates a side view of the inhaler of Figure 1, illustrated with the blister pack assembly separated from the support unit;

Figure 5 illustrates a plan view of the inhaler of Figure 1, illustrated with the blister pack assembly partially loaded into/unloaded from the support unit;

Figure 6 illustrates a side view of the inhaler of Figure 1, illustrated with the blister pack assembly partially loaded into/unloaded from the support unit;

Figure 7 illustrates a plan view of the inhaler of Figure 1, illustrated with the blister pack assembly loaded in the support unit;

Figure 8 illustrates a side view of the inhaler of Figure 1, illustrated with the blister pack assembly loaded in the support unit;

Figure 9 illustrates in enlarged scale a fragmentary vertical sectional view (along section I-I in Figure 1) of the inhaler of Figure 1;

Figure 10 illustrates in enlarged scale a fragmentary vertical sectional view (along section II-II in Figure 1) of the inhaler of Figure 1;

Figure 11 illustrates in enlarged a fragmentary vertical sectional view (along section III-III in Figure 1) of the inhaler of Figure 1;

Figure 12 illustrates a perspective view of the blister pack assembly of the inhaler of Figure 1;

Figure 13 illustrates in enlarged scale a fragmentary exploded perspective view of the blister pack unit of the blister pack assembly of Figure 12;

Figure 14 illustrates a fragmentary vertical sectional view (along section IV-IV in Figure 13) of the blister pack unit of Figure 13;

Figure 15 illustrates a fragmentary vertical sectional view (along section V-V in Figure 13) of the blister pack unit of Figure 13;

Figure 16(a) illustrates in enlarged scale a plan view of the blister pack element of the blister pack assembly of Figure 12;

Figure 16(b) illustrates an underneath plan view of the blister pack element of Figure 16(a);

Figure 16(c) illustrates a side view of the blister pack element of Figure 16(a);

Figure 16(d) illustrates one end view of the blister pack element of Figure 16(a);

Figure 16(e) illustrates the other end view of the blister pack element of Figure 16(a);

Figure 16(f) illustrates a vertical sectional view (along section VI-VI in Figure 16(a)) of the blister pack element of Figure 16(a);

Figure 16(g) illustrates a vertical sectional view (along section VII-VII in Figure 16(a)) of the blister pack element of Figure 16(a);

Figure 17(a) illustrates in enlarged scale a plan view of the attachment member of the blister pack unit of the blister pack assembly of Figure 12;

Figure 17(b) illustrates an underneath plan view of the attachment member of Figure 17(a);

Figure 17(c) illustrates an end view of the attachment member of Figure 17(a);

Figure 17(d) illustrates one side view of the attachment member of Figure 17(a);

Figure 17(e) illustrates the other side view of the attachment member of Figure 17(a);

Figure 18(a) illustrates in enlarged scale a first side view of the suction tube of the blister pack assembly of Figure 12;

Figure 18(b) illustrates a second, orthogonal side view of the suction tube of Figure 18(a);

Figure 18(c) illustrates a plan view of the suction tube of Figure 18(a);

Figure 18(d) illustrates an underneath plan view of the suction tube of Figure 18(a);

Figure 18(e) illustrates a fragmentary perspective view of the suction tube of Figure 18(a);

Figure 18(f) illustrates a vertical sectional view (along section VIII-VIII in Figure 18(a)) of the suction tube of Figure 18(a);

Figure 18(g) illustrates a vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a);

Figure 19(a) illustrates a plan view of the interconnecting member of the blister pack assembly of Figure 12;

Figure 19(b) illustrates a side view of the interconnecting member of Figure 19(a);

Figure 20(a) illustrates a plan view of the support unit of the inhaler of Figure 1; illustrated in the closed or storage configuration;

Figure 20(b) illustrates a side view of the support unit of Figure 20(a), illustrated in the closed or storage configuration;

Figure 20(c) illustrates one end view of the support unit of Figure 20(a), illustrated in the closed or storage configuration;

Figure 20(d) illustrates the other end view of the support unit of Figure 20(a), illustrated in the closed or storage configuration;

Figure 20(e) illustrates a plan view of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(f) illustrates a side view of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(g) illustrates in enlarged scale a vertical sectional view (along section X-X in Figure 20(e)) of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(h) illustrates in enlarged scale a vertical sectional view (along section XI-XI in Figure 20(e)) of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 20(i) illustrates in enlarged scale a vertical sectional view (along section XII-XII in Figure 20(e)) of the support unit of Figure 20(a), illustrated in the open or operative configuration;

Figure 21(a) illustrates a fragmentary vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a) when partly inserted into a blister;

Figure 21(b) illustrates a horizontal sectional view (along section XIII-XIII in Figure 21(a)) of the suction tube of Figure 18(a) when partly inserted into a blister;

Figure 22(a) illustrates a fragmentary vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a) when further inserted into a blister;

Figure 22(b) illustrates a horizontal sectional view (along section XIV-XIV in Figure 22(a)) of the suction tube of Figure 18(a) when further inserted into a blister;

Figure 23(a) illustrates a fragmentary vertical sectional view (along section IX-IX in Figure 18(b)) of the suction tube of Figure 18(a) when fully inserted into a blister;

Figure 23(b) illustrates a horizontal sectional view (along section XV-XV in Figure 23(a)) of the suction tube of Figure 18(a) when fully inserted into a blister;

Figure 24(a) illustrates a fragmentary perspective view of a first modified suction tube for the inhaler of Figure 1;

Figure 24(b) illustrates a vertical sectional view (along section XVI-XVI in Figure 24(a)) of the suction tube of Figure 24(a);

Figure 24(c) illustrates a vertical sectional view (along section XVII-XVII in Figure 24(a)) of the suction tube of Figure 24(a);

Figure 25(a) illustrates a fragmentary perspective view of a second modified suction tube for the inhaler of Figure 1;

Figure 25(b) illustrates a vertical sectional view (along section XVIII-XVIII in Figure 25(a)) of the suction tube of Figure 25(a);

Figure 25(c) illustrates a vertical sectional view (along section XIX-XIX in Figure 25(a)) of the suction tube of Figure 25(a);

Figure 26(a) illustrates a fragmentary perspective view of a third modified suction tube for the inhaler of Figure 1;

Figure 26(b) illustrates a vertical sectional view (along section XX-XX in Figure 26(a)) of the suction tube of Figure 26(a);

Figure 26(c) illustrates a vertical sectional view (along section XXI-XXI in Figure 26(a)) of the suction tube of Figure 26(a);

Figure 27(a) illustrates a fragmentary perspective view of a fourth modified suction tube for the inhaler of Figure 1;

Figure 27(b) illustrates a vertical sectional view (along section XXII-XXII in Figure 27(a)) of the suction tube of Figure 27(a);

Figure 27(c) illustrates a vertical sectional view (along section XXIII-XXIII in Figure 27(a)) of the suction tube of Figure 27(a);

Figure 28 illustrates a perspective view of a modified blister pack assembly for the inhaler of Figure 1;

Figure 29 illustrates in enlarged scale a fragmentary perspective view of the blister pack unit of the blister pack assembly of Figure 28;

Figure 30 illustrates in enlarged scale a fragmentary exploded perspective view of the blister pack unit of the blister pack assembly of Figure 28;

Figure 31 illustrates an exploded vertical sectional view (along section XXIV-XXIV in Figure 28) of the blister pack unit of the blister pack assembly of Figure 28; and

Figure 32 illustrates an exploded vertical sectional view (along section XXV-XXV in Figure 28) of the blister pack unit of the blister pack assembly of Figure 28.

The inhaler comprises a support unit 1 and a blister pack assembly 3 which in use is fitted thereto.

The blister pack assembly 3 comprises a blister pack unit 5, a suction tube 7 and an interconnecting member 9 which connects the suction tube 7 to the blister pack unit 5 so as

to prevent the suction tube 7 from being inadvertently separated from the blister pack unit 5.

The blister pack unit 5 comprises a blister pack element 11, in this embodiment of generally rectangular shape, which includes a plurality of blisters 12, each containing a dose of powder containing medicament, and an attachment member 13, to which the suction tube 7 is attachable, fixed to the blister pack element 11.

The blister pack element 11 comprises a substantially planar thin sheet 17 which includes a plurality of cavities 19, each defining a part of a respective blister 12, and first and second open channels 21, 23 which are separated by a web member 25 and extend along the longitudinal axis of the blister pack element 11. In this embodiment the sheet 17 is formed of a metal, such as aluminium, and the cavities 19 have a depth of about 4 mm and a diameter at the opening thereof of about 7.5 mm. In alternative embodiments the sheet 17 can be formed of a plastics material or a laminate of metal and plastics material. The first channel 21, in this embodiment a flattened U-shaped section, comprises first and second opposed side wall members 21a, 21b and a bottom wall member 21c. The first channel 21 is of relatively short length and extends to one narrow end 22 of the blister pack element 11 so as to allow for a sliding fit thereto of mutually configured parts of the attachment member 13 as will be described in more detail hereinbelow. The bottom wall member 21c of the first channel 21 includes a downwardly-directed projection 29 which acts as a detent for fixing the attachment member 13 in position relative to the blister pack element 11 as again will be described in more detail hereinbelow. The second channel 23, in this embodiment of arcuate section, is elongate and includes first and second end wall members 23a, 23b. The web member 25 separating the first and second channels 21, 23 includes a groove 35 which extends across the width thereof and along the longitudinal axis of the blister pack element 11.

The blister pack element 11 further comprises a thin film 37, in this embodiment in two sections, which is attached to the substantially planar surface of the sheet 17 thereof so as

to cover the openings of each of the cavities 19 and thereby enclose a dose of powder containing medicament in each blister 12. In this embodiment the film 37 is formed of a metal, such as aluminium, and is attached to the sheet 17 by one of welding or an adhesive.

The attachment member 13 comprises an elongate body 39 which is of substantially the same length as the one narrow end 22 of the blister pack element 11, first and second projections 41, 43 which extend from the mid-point of one side surface of the elongate body 39 and together define a U-shaped channel 45 for receiving the first channel 21 in the sheet 17 of the blister pack element 11 and first and second clips 47, 49 which extend from the respective ends of the other side surface of the elongate body 39 and are each separately configured to hold the suction tube 7 when not in use. In this embodiment the clips 47, 49 are configured such that when the suction tube 7 is attached to one of the clips 47, 49 the other of the clips 47, 49 acts as a guard to protect against damage of the suction tube 7. The first projection 41, in this embodiment of rectangular section, is of the same section as the upper, inner surface of the first channel 21 in the sheet 17 of the blister pack element 11 so as to be a close slideable fit therein and includes a groove 42 which extends along the upper surface of the length thereof. The second projection 43, in this embodiment a flattened U-shaped section, comprises first and second opposed side wall members 43a, 43b and a bottom wall member 43c, with the first and second projections 41, 43 being configured such that the first and second side wall members 43a, 43b and the bottom wall member 43c of the second projection 43 are disposed opposite the side and bottom surfaces of the first projection 41. The upper, inner surface of the second projection 43 is of the same section as the outer, lower surface of the first channel 21 in the sheet 17 of the blister pack element 11 so as to be a close slideable fit thereabout, with the side wall members 43a, 43b of the second projection 43 being dimensioned so as to abut a lower surface of the sheet 17 of the blister pack element 11. The bottom wall member 43c of the second projection 43 includes an opening 51 therein for receiving the downwardly-directed projection 29 on the bottom wall member 21c of the first channel 21 in the sheet 17 of the blister pack element 11 when the attachment member 13 is fitted to the blister pack

element 11 so as to fix the attachment member 13 in position relative to the blister pack element 11.

The suction tube 7, which will be described in further detail hereinbelow, comprises a generally elongate body 62 which includes an inlet section 63 at one end, which inlet section 63 includes a cutting assembly 64 for cutting the film 37 covering the cavities 19 of the blisters 12 in the blister pack element 11 and an inlet 65 through which powder containing medicament is in use drawn from a respective blister 12 on inhalation by a user, an outlet section 67 at the other end, which outlet section 67 includes an outlet 69 and provides a mouthpiece, and an inhalation channel 71 providing fluid communication between the inlet 65 and the outlet 69. The body 62 of the suction tube 7 includes at the outer surface thereof a plurality of ribs 73 for allowing a user to grip the same securely and a peripheral recess 75 for receiving a part of the interconnecting member 9 as will be described in more detail hereinbelow.

The interconnecting member 9 comprises a line 76 of a flexible material, preferably a plastics material, such as nylon, a clip 77 fixed to one end of the line 76 which is located in the peripheral recess 75 in the outer surface of the body 62 of suction tube 7 so as to anchor the line 76 to the same and an element 79 fixed at the other end of the line 76 which is of larger dimension than the gauge of the line 76 and is in use located partly in the second channel 21 in the sheet 17 of the blister pack element 11. In this embodiment the clip 77 is part-circular and formed of a resilient material so as to be a snap-fit about the body 62 of the suction tube 7. With this configuration, the line 76 is anchored to the suction tube 7 but yet allows the suction tube 7 to rotate relative thereto. As will become apparent hereinbelow, the suction tube 7, in being rotatable relative to the clip 77 of the interconnecting member 9, has a much greater freedom of movement and thereby facilitates use.

The support unit 1 comprises a housing 81 which includes an opening 82 and defines a cavity 83 into which the blister pack element 11 of the blister pack assembly 3 is in use inserted and a cover member 84 for enclosing the blister pack assembly 3 when not in use.

The housing 81 comprises a first, upper wall member 85 which, in this embodiment, is substantially planar and of rectangular shape. The upper wall member 85 includes an upper, outer surface 85a and a lower, inner surface 85b adjacent which the blister pack element 11 of the blister pack assembly 3 is in use disposed. The upper wall member 85 also includes one free end 86 which defines a part of the opening 82 in the housing 81 through which the blister pack element 11 is in use inserted. The upper wall member 85 further includes a plurality of openings 87 which each overlie a respective one of the openings of the cavities 19 of the blisters 12 in the blister pack element 11 such that each of the blisters 12 can be emptied by inserting the suction tube 7 into a respective one of the openings 87. In this embodiment the openings 87 in the upper wall member 85 are each configured to have the same peripheral shape as the inlet section 63 of the suction tube 7 such that the openings 87 act as guides for guiding the inlet section 63 of the suction tube 7 into a respective blister 12 in the blister pack element 11. Each of the openings 87 includes first and second radial extensions 87a, 87b for receiving mutually configured parts on the inlet section 63 of the suction tube 7 as will be described hereinbelow. The radial extensions 87a, 87b of the openings 87 each include a web member 89 which includes upper and lower surfaces 89a, 89b that are substantially parallel respectively to the upper and lower surfaces 85a, 85b of the upper wall member 85 of the housing 81. The web members 89 are of lesser thickness than the upper wall member 85 of the housing 81 and are disposed such that the upper and lower surfaces 89a, 89b thereof are stepped back respectively from the upper and lower surfaces 85a, 85b of the upper wall member 85. The upper wall member 85 of the housing 81 further includes an elongate slot 91 which extends from the one free end 86 thereof, in this embodiment along the longitudinal axis of the housing 81, and overlies the second channel 23 in the sheet 17 of the blister pack element 11 when fitted such that the line 76 of the interconnecting member 9 can be drawn thereinto and pass freely therealong. The elongate slot 91 includes a first, narrow section

91a at the upper surface 85a of the upper wall member 85 which is of a width smaller than the smallest dimension of the element 79 of the interconnecting member 9 so as to prevent that element 79 from passing therethrough and a second, wide section 91b at the lower surface 85b of the upper wall member 85 for receiving a part of the element 79 of the interconnecting member 9. In this embodiment the wide section 91b of the elongate slot 91 is arcuate in shape and flares outwardly to the lower surface 85b of the upper wall member 85. The upper wall member 85 still further includes a plurality of elongate ribs 93 which extend downwardly from the lower surface 85b thereof parallel to the longitudinal axis of the housing 81. The ribs 93 are provided to space the upper surface of the blister pack element 11 from the lower surface 85a of the upper wall member 85 and thereby provide an air flow path to the blisters 12 in the blister pack element 11. Further, in this embodiment one rib 93 is located on either side of the elongate slot 91 in the upper wall member 85 such that when the blister pack assembly 3 is fitted to the support unit 1 the second channel 23 in the sheet 17 of the blister pack element 11 and the wide section 91b of the elongate slot 91 define an enclosed track in which the element 79 of the interconnecting member 9 is captively held, with the limits of movement of the element 79 along the enclosed track being defined by the end wall members 23a, 23b of the second channel 23 in the sheet 17 of the blister pack element 11. It will be appreciated that this configuration, in not having the line 76 of the interconnecting member 9 fixed at one point, is advantageous in that the line 76 of the interconnecting member 9 need only be as long as the distance between the furthestmost opening 87 and the elongate slot 91 in the upper wall member 85, which distance in this embodiment corresponds to approximately half of the width of the upper wall member 85. The upper wall member 85 still further includes a recess 94 at that end thereof remote from the opening 82 in the housing 81. This recess 94 provides a means by which a user can push the blister pack element 11 a distance out of the housing 81 so as to facilitate withdrawal of the blister pack assembly 3.

The housing 81 further comprises a second, lower wall member 95, in this embodiment substantially planar and of rectangular shape, which is spaced in parallel relation to the upper wall member 85, first and second side wall members 97, 99 which extend between

the sides of the upper and lower wall members 85, 95 and an end wall member 101 which extends between the ends of the upper and lower wall members 85, 95 remote from the opening 82 in the housing 81. In this embodiment the side wall members 97, 99 and the end wall member 101 each include a groove 97', 99', 101' into which the peripheral edge at the sides and the other end of the blister pack element 11 of the blister pack assembly 3 is in use located such that the blister pack element 11 is held in position adjacent the lower surface 85b of the upper wall member 85 of the housing 81.

The cover member 84 is hinged to the housing 81, in this embodiment at that end adjacent the opening 82 therein. In a preferred embodiment the housing 81 and the cover member 84 of the support unit 1 are integrally formed of a plastics material such that the hinged connection of the housing 81 and the cover member 84 is provided by a living hinge. The cover member 84 includes a catch member 102 at the free end thereof which is configured to engage the recess 94 in the upper wall member 85 of the housing 81 when the cover member 84 is closed and thereby hold the same closed.

As described hereinabove, the suction tube 7 includes an inlet section 63 which includes a cutting assembly 64 for cutting the film 37 covering the cavities 19 of the blisters 12 in the blister pack element 11.

The inlet section 63 of the suction tube 7 further includes first and second arms 105, 107 which extend forwardly, in the sense of insertion of the suction tube 7 into a blister 12 in the blister pack element 11, from respective sides thereof and are biased outwardly. The arms 105, 107 are each configured so as to be a sliding fit in the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81. In this way, the suction tube 7 can only be inserted into an opening 87 in the upper wall member 85 of the housing 81 in one of two orientations and, as will become apparent hereinbelow, since the cutting assembly 64 has two-fold rotational symmetry, the suction tube 7 can never inadvertently be inserted into a blister 12 with another orientation which may cause the film 37 covering the respective blister 12 to be cut free. It will, of course, be appreciated that in any

embodiment where the cutting assembly 64 of the suction tube 7 does not have such rotational symmetry the first and second arms 105, 107 at the inlet section 63 and the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81 can be configured so as to permit the suction tube 7 to be inserted into the openings 87 in the upper wall member 85 of the housing 81 in only one orientation. Each of the first and second arms 105, 107 includes a catch member 109, 111 which is adapted to engage with the web members 89 in the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81. The catch members 109, 111 on the first and second arms 105, 107 each have a first surface 109a, 111a which has a forwardly-directed component and acts as a guiding surface and a second surface 109b, 111b which is substantially orthogonally directed to the longitudinal axis of the body 62 of the suction tube 7 and acts as a locking surface. In use, on fitting the suction tube 7 to the housing 81, the second, locking surfaces 109b, 111b of the catch members 109, 111 snap behind respective ones of the lower surfaces 89b of the web members 89 in the radial extensions 87a, 87b of the openings 87 in the upper wall member 85 of the housing 81 so as to prevent the suction tube 7 from falling out of the respective opening 87 and thereby avoid the need for the user continuously to hold the suction tube 7 in position. It will be appreciated that the catch members 109, 111, in being a snap fit, provide the user with a clear indication that the suction tube 7 is correctly fitted to the housing 81 and hence inserted into a respective one of the blisters 12 in the blister pack element 11. In this regard, the second, locking surfaces 109b, 111b of the catch members 109, 111 are configured so as to have only a small radial extent such as to allow the suction tube 7 to be removed from a respective one of the openings 87 in the upper wall member 85 of the housing 81 after use on the application of a light force.

The inlet section 63 of the suction tube 7 yet further includes a plurality of lugs 115 which extend radially therefrom and each include a lower surface 115' which defines a first shoulder that acts to limit the extent to which the suction tube 7 can be inserted into any of the openings 87 in the upper wall member 85 of the housing 81 and hence a respective blister 12 in the blister pack element 11. In this embodiment the lugs 115 are configured

such that the shoulder defined by the lower surfaces 115' thereof abuts the upper surface 85a of the upper wall member 85 of the housing 81 on the required insertion of the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81. In this way, the suction tube 7 cannot be inserted too far into a blister 12 which could result in the cutting assembly 64 at the inlet section 63 of the suction tube 7 being forced inadvertently through the cavity 19 of any blister 12 on fitting the suction tube 7 to the housing 81.

The inlet section 63 of the suction tube 7 still further includes first and second axially-extending members 117, 119 which each include a lower surface 117', 119' that defines a second shoulder which is axially forward, in the sense of inserting the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, of the first shoulder defined by the lower surfaces 115' of the lugs 115. In this embodiment the first and second axially-extending members 117, 119 are configured such that the second shoulder defined by the lower surfaces 117', 119' thereof abuts the upper surface of the blister pack element 11 when the first shoulder defined by the lower surfaces 115' of the lugs 115 abuts the upper surface 85a of the upper wall member 85 of the housing 81.

The cutting assembly 64 of the inlet section 63 of the suction tube 7 comprises a cutting blade 127 and first and second ram blades 129, 131 disposed adjacent thereto.

The cutting blade 127 includes a cutting edge 133 which extends across and is located axially forward, in the sense of inserting the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, of the inlet 65 of the suction tube 7 such that, on insertion of the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, a cut is made in the film 37 covering the opening of the cavity 19 of the blister 12 therebeneath. In this embodiment the cutting edge 133 of the cutting blade 127 includes a cutting point 133'. The cutting blade 127, which in this embodiment is substantially planar, is co-axial with the longitudinal axis of the body 62 of the suction tube 7 and includes first and second flank sections 127a, 127b which taper to an axially-foremost cutting point 127c located on the longitudinal axis of the body 62 of the suction

tube 7. In this embodiment the flank sections 127a, 127b of the cutting blade 127 enclose an angle of about 120 degrees. The cutting blade 127 has an effective cutting length approaching that of the diameter of the openings to the cavities 19 of the blisters 12 in the blister pack element 11 such that, on insertion of the suction tube 7 into a respective one of the openings 87 in the upper wall member 85 of the housing 81, the cutting blade 127 cuts the film 37 across the diameter of the opening to the cavity 19 of the respective blister 12. The cutting blade 127 further includes a transverse opening 134 located behind the cutting edge 133 thereof for providing an air flow path therethrough.

The first and second ram blades 129, 131, which in this embodiment are each substantially planar, are located to each side of the cutting blade 127 and, as will be described in more detail hereinbelow, are configured to bear on and push back the film 37 covering the cavity 19 of a respective one of the blisters 12 once cut by the cutting blade 127 and thereby open the blister 12. In this embodiment the first and second ram blades 129, 131 are disposed parallel to, and are the same radial distance from, the cutting blade 127. The first and second ram blades 129, 131 each include a lower, axially-forward surface 129', 131' which is located axially rearward of the axially foremost part of the cutting edge 133 of the cutting blade 127 such that the ram blades 129, 131 act on the film 37 only once at least partly cut by the cutting blade 127. In this embodiment the bearing surface 129', 131' of each of the ram blades 129, 131 is substantially flat.

In a preferred embodiment the cutting assembly 64 is configured such that the effective length of each of the bearing surfaces 129', 131' of the ram blades 129, 131, that is, the distance between the endmost points of the bearing surface 129', 131' of each of the ram blades 129, 131, is approximately the same distance as the distance between the adjacent endmost points of the bearing surfaces 129', 131' of the ram blades 129, 131 and the endmost points of the effective cutting length of the cutting blade 127. In this way, the film 37 covering the openings of the cavities 19 of any of the blisters 12 in the blister pack element 11 will be broken into flaps 136a-f of substantially equal size.

The action of the cutting assembly 64 at the inlet section 63 of the suction tube 7 is clearly illustrated in Figures 21 to 23. In a first step, as illustrated in Figures 21(a) and 21(b), as the cutting assembly 64 is inserted into a blister 12 the cutting blade 127 makes a cut 135 across the diameter of the film 37 covering the opening of the cavity 19 of the blister 12. In a second step, as illustrated in Figures 22(a) and 22(b), as the cutting assembly 64 is inserted further into the blister 12 the bearing surfaces 129', 131' of the ram blades 129, 131 act on the film 37 and cause the film 37 to tear between adjacent endmost points of the bearing surface 129', 131' of the ram blades 129, 131 and the ends 135' of the cut 135 so as to form six flaps 136a-f. As mentioned hereinabove, in a preferred embodiment the cutting blade 127 and the ram blades 129, 131 are configured such that the flaps 136a-f are of substantially equal size. In a final step, as illustrated in Figures 23(a) and 23(b), the cutting assembly 64 is inserted further into the blister 12 until the second shoulder defined by the lower surfaces 117', 119' of the axially-directed members 117, 119 is at the upper surface of the blister pack element 11. In this position the suction tube 7 is inserted fully into the blister 12. In inserting the cutting assembly 64 further into blister 12 the ram blades 129, 131 cause the flaps 136a-f to be pushed to the wall of the cavity 19 of the blister 12 so as to provide a large opening in the film 37 covering the blister 12 which allows for the ready withdrawal of powder therefrom.

The inlet section 63 of the suction tube 7 still yet further includes first and second upper supplementary air inlet openings 137, 139 into the inhalation channel 71 of the suction tube 7. The first and second upper supplementary air inlet openings 137, 139 into the inhalation channel 71 provide supplementary air flow paths which, on inhalation by a user, allow supplementary air to be drawn into the inhalation channel 71 and mix with the air and powder mixture drawn through the inhalation channel 71 from a blister 12 in the blister pack element 11. As will be appreciated, the provision of such supplementary air flow paths provides that for each unit volume of air inhaled the user inhales a reduced amount of powder containing medicament. Furthermore, the action of supplementary air mixing with an air and powder mixture drawn through the inhalation channel 71 induces turbulence and assists in the deagglomeration of that powder.

Figures 24 to 27 illustrate modified suction tubes 7 for the inhaler described hereinabove. Structurally, these modified suction tubes 7 are similar to the suction tube 7 of the inhaler described hereinabove and differ only in aspects of the inlet section 63, principally the cutting assembly 64. For this reason, and in order to avoid unnecessary duplication of description, only the structural differences of the suction tubes 7 will be described in detail and reference is made to the preceding description.

Figures 24(a) to (c) illustrate a first modified suction tube 7. This suction tube 7 differs from the first-mentioned suction tube 7 in two aspects. Firstly, the ram blades 129, 131 each include an opening 141, 143 which extends axially rearwardly from the bearing surface 129', 131' thereof for providing shorter air flow paths between the periphery of the cavity 19 of the blister 12 adjacent the ram blades 129, 131 and the inlet 65. Secondly, the inlet 65 to the inhalation channel 71 is located axially forward, in the sense of insertion of the suction tube 7 into a blister 12, of the shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. With this configuration, the inlet 65 to the inhalation channel 71 is located within each blister 12 and thereby forces air to be drawn more deeply into the cavity 19 of the blister 12 on inhalation by a user.

Figures 25(a) to (c) illustrate a second modified suction tube 7. This suction tube 7 differs from the first-modified suction tube 7 in that the transverse opening 141, 143 in each of the ram blades 129, 131 is within the respective ram blade 129, 131.

Figures 26(a) to (c) illustrate a third modified suction tube 7. This suction tube 7 differs from the first-mentioned suction tube 7 in two aspects. Firstly, the inlet section 63 of the suction tube 7 further includes first and second lower supplementary air inlet openings 147, 149 into the inhalation channel 71 at a position adjacent, but in this embodiment axially rearward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117,

119 which in use is located at the upper surface of the blister pack element 11. These first and second lower supplementary air inlet openings 147, 149 provide a supplementary air flow path into the inhalation channel 71 which promotes turbulent flow within the cavity 19 of the blister 12, which turbulence as will be appreciated assists in emptying the blister 12. Secondly, the inlet 65 to the inhalation channel 71 is located axially forward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. As described hereinabove in relation to the first-modified suction tube 7, with this configuration the inlet 65 to the inhalation channel 71 is located within each blister 12 and thereby forces air to be drawn more deeply into the cavity 19 of the blister 12 on inhalation by a user.

Figures 27(a) to (c) illustrate a fourth modified suction tube 7. This suction tube 7 differs from the first-mentioned suction tube 7 in two aspects. Firstly, the ram blades 129, 131 each include a transverse opening 141, 143 which extends to the bearing surface 129', 131' thereof for providing shorter air flow paths between the periphery of the cavity 19 of the blister 12 adjacent the ram blades 129, 131 and the inlet 65. In this embodiment the openings 141, 143 in the ram blades 129, 131 are asymmetrically located so as to promote turbulent flow in the cavities 19 of the blisters 12. Secondly, the inlet 65 to the inhalation channel 71 is located axially forward, in the sense of insertion of the suction tube 7 into a blister 12, of the second shoulder defined by the lower surfaces 117', 119' of the axially-extending members 117, 119 which in use is located at the upper surface of the blister pack element 11. As again described hereinabove in relation to the first-modified suction tube 7, with this configuration the inlet 65 to the inhalation channel 71 is located within each blister 12 and thereby forces air to be drawn more deeply into the cavity 19 of the blister 12 on inhalation by a user.

Figures 28 to 32 illustrate a modified blister pack assembly 3 for the inhaler described hereinabove. Structurally, this modified blister pack assembly 3 is similar to the blister pack assembly 3 of the inhaler described hereinabove and differs only in aspects of the

blister pack unit 5. For this reason, and in order to avoid unnecessary duplication of description, only the structural differences of the blister pack assemblies 3 will be described in detail and reference is made to the preceding description. This modified blister pack unit 5 differs principally from the blister pack unit 5 of the blister pack assembly 3 of the inhaler described hereinabove in that the sheet 17 of the blister pack element 11 includes a downwardly-depending peripheral skirt 151 and a plurality of downwardly-directed elongate ribs 153 which extend parallel to the longitudinal axis of the blister pack unit 11. With this configuration the blister pack element 11 is configured to be a sliding fit in the cavity 83 of the housing 81 of the support unit 1, with the blister pack element 11 being self-supporting by the provision of the skirt 151 and the ribs 153. This modified blister pack unit 5 further differs from the blister pack unit 5 of the blister pack assembly 3 of the inhaler described hereinabove in the manner of the connection of the attachment member 13 in that the blister pack element 11 includes first and second projections 155, 157 at the one end 22 thereof to which the attachment member 13, which is also modified in not including the first and second projections 41, 43, is snap fitted. This modified blister pack unit 5 yet further differs from the blister pack unit 5 of the blister pack assembly 3 of the inhaler described hereinabove in further including moisture-permeable chambers 159 which contain desiccant disposed to the lower surface of the sheet 17 thereof at at least some of the junctions between the cavities 19 defining the blisters 12 and in including a thin film 161 covering the lower surface thereof.

In use, a user takes the inhaler in one hand and opens up the cover member 84 of the support unit 1 so as to expose the suction tube 7 and the upper wall member 85 of the housing 81. The user then unclips the suction tube 7 from the attachment member 13 and inserts the inlet section 63 of the suction tube 7 through one of the openings 87 in the upper wall member 85 of the housing 81 and into an unused blister 12. In inserting the inlet section 63 of the suction tube 7 into one of the openings 87 in the upper wall member 85 of the housing 81, the user has first to align the arms 105, 107 thereon with the radial extensions 87a, 87b of the openings 87 and then push in the suction tube 7 until the first shoulder defined by the lower surfaces 115' of the lugs 115 abuts the upper surface 85a of

the upper wall member 85 and the catches 109, 111 on the arms 105, 107 snap behind the web members 89 in the radial extensions 87a, 87b of the openings 87. The user then takes the mouthpiece provided by the outlet section 67 of the suction tube 7 in his/her lips and inhales so as to withdraw the dose of powder containing powder from the blister 12 and deliver the same into the lungs. After inhalation, the user withdraws the suction tube 7 from the opening 87 in the upper wall member 85 of the housing 81, which will require the application of a light force to overcome the action of the catches 109, 111 on the arms 105, 107 of the suction tube 7, and then clips the suction tube 7 back to the attachment member 13. This pattern of use can be repeated until all of the blisters 12 in the blister pack element 11 of the blister pack assembly 3 have been used. When all of the blisters 12 in the blister pack element 11 have been used, the user withdraws the blister pack assembly 3 form the support unit 1 and replaces that used blister pack assembly 3 with a new blister pack assembly 3.

Finally, it will be understood by a person skilled in the art that the present invention is not limited to the described embodiments but can be modified in many different ways without departing from the scope of the invention as defined in the appended claims.

CLAIMS

1. A suction tube for administering powder containing medicament from a blister (12) comprising a cavity (19) sealed by a covering film (37), the suction tube comprising an elongate body (62) which includes an inlet section (63) at one end thereof, which inlet section (63) includes an inlet (65) and a cutting assembly (64) comprising a cutting blade (127) which includes a cutting edge (133) for making a cut in the covering film (37) of a blister (12) and at least one ram blade (129, 131) which includes a bearing surface (129', 131') for bearing on the covering film (37) of the blister (12) and pushing the same into the cavity (19) of the blister (12), an outlet section (67) at the other end thereof, which outlet section (67) includes an outlet (69) and provides a mouthpiece, and an inhalation channel (71) providing fluid communication between the inlet (65) and the outlet (69) through which powder is in use drawn on inhalation by a user.

2. The suction tube according to claim 1, wherein the cutting edge (133) of the cutting blade (127) extends axially forward of the bearing surface (129', 131') of the at least one ram blade (129, 131) such that the covering film (37) of a blister (12) is at least partly cut by the cutting blade (127) before the bearing surface (129', 131') of the at least one ram blade (129, 131) contacts the covering film (37) of the blister (12).

3. The suction tube according to claim 2, wherein the cutting blade (127) is disposed axially forward of the bearing surface (129', 131') of the at least one ram blade (129, 131) such that the covering film (37) of a blister (12) is cut by the cutting blade (127) before the bearing surface (129', 131') of the at least one ram blade (129, 131) contacts the covering film (37) of the blister (12).

4. The suction tube according to any of claims 1 to 3, wherein the cutting blade (127) extends across the inlet (65).

5. The suction tube according to any of claims 1 to 4, wherein the inlet (65) is substantially co-axial with the longitudinal axis of the body (62).

6. The suction tube according to any of claims 1 to 5, wherein the cutting blade (127) is substantially co-axial with the longitudinal axis of the body (62).

7. The suction tube according to any of claims 1 to 6, wherein the cutting blade (127) includes at least one cutting point (127c).

8. The suction tube according to claim 7, wherein the cutting blade (127) includes first and second sections (127a, 127b) which taper to a cutting point (127c).

9. The suction tube according to any of claims 1 to 8, wherein the cutting blade (127) includes at least one transverse opening (134) axially rearward of the cutting edge (133) thereof.

10. The suction tube according to any of claims 1 to 9, wherein the cutting blade (127) is substantially planar.

11. The suction tube according to any of claims 1 to 10, wherein each ram blade (129, 131) includes at least one transverse opening (141, 143).

12. The suction tube according to claim 11, wherein the at least one transverse opening (141, 143) is axially rearward of the bearing surface (129', 131') of the ram blade (129, 131).

13. The suction tube according to claim 11, wherein the at least one transverse opening (141, 143) extends axially rearwardly from the bearing surface (129', 131') of the ram blade (129, 131).

14. The suction tube according to any of claims 11 to 13, wherein the at least one transverse opening (141, 143) is asymmetrically located in the ram blade (129, 131).

15. The suction tube according to claim 14, wherein the at least one ram blade (129, 131) is substantially planar.

16. The suction tube according to any of claims 1 to 15, wherein the inlet section (63) includes supplementary air inlet openings (147, 149) into the inhalation channel (71) at an axial position rearwardly adjacent the inlet (65).

17. The suction tube according to any of claims 1 to 16, wherein the cutting assembly (64) includes first and second ram blades (129, 131) disposed on opposite sides of the cutting blade (127).

18. The suction tube according to claim 17, wherein each ram blade (129, 131) is disposed substantially the same radial distance from the cutting blade (127).

19. The suction tube according to claim 17 or 18, wherein the cutting assembly (64) is configured such that the distance between the endmost points of the bearing surface (129', 131') of each of the ram blades (129, 131) is approximately the same distance as the distance between the endmost points of the effective cutting length of the cutting blade (127) and the adjacent endmost points of the bearing surface (129', 131') of each of the ram blades (129, 131).

20. The suction tube according to any of claims 1 to 19, wherein the axial position of the inlet (65) is such that when the inlet section (63) is located in a blister (12) the inlet (65) is located below the surface defining the opening of the cavity (19) of the blister (12).

21. The suction tube according to any of claims 1 to 20, wherein the inlet section (63) includes at least one surface (117', 119') which defines a shoulder which in use is located at the upper surface of the blister (12).

22. An inhaler for administering dry powder by inhalation, comprising the suction tube (7) according to any of claims 1 to 21.

23. The inhaler according to claim 22, further comprising a support unit (1) for supporting a blister pack element (11), wherein the support unit (1) includes a wall member (85) which includes a plurality of openings (87) adjacent which the blister pack element (11) is in use disposed such that a blister (12) is located beneath each opening (87).

24. The inhaler according to claim 23, wherein the inlet section (63) of the suction tube (7) includes at least one surface (115') which defines a shoulder that acts to limit the extent to which the suction tube (7) can be inserted into the openings (87) in the wall member (85).

25. The inhaler according to claim 23 or 24, wherein the openings (87) in the wall member (85) of the support unit (1) each include at least one radial extension (87a, 87b) which each include a web member (89) and the inlet section (63) of the suction tube (7) includes at least one resiliently-biased arm (105, 107) which supports a catch member (109, 111) and is configured to fit into the at least one radial extension (87a, 87b) of the openings (87) in the wall member (85), with the catch member (109, 111) and the web member (89) being configured to engage one another when the suction tube (7) is inserted into one of the openings (87) in the wall member (85).

26. The inhaler according to claim 25, wherein the openings (87) in the wall member (85) of the support unit (1) each include first and second radial extensions (87a, 87b) and the inlet section (63) of the suction tube (7) includes first and second resiliently-biased arms (105, 107).

27. The inhaler according to claim 26, wherein the first and second radial extensions (87a, 87b) of the openings (87) in the wall member (85) and the first and second arms (105, 107) of the inlet section (63) of the suction tube (7) are radially opposed.

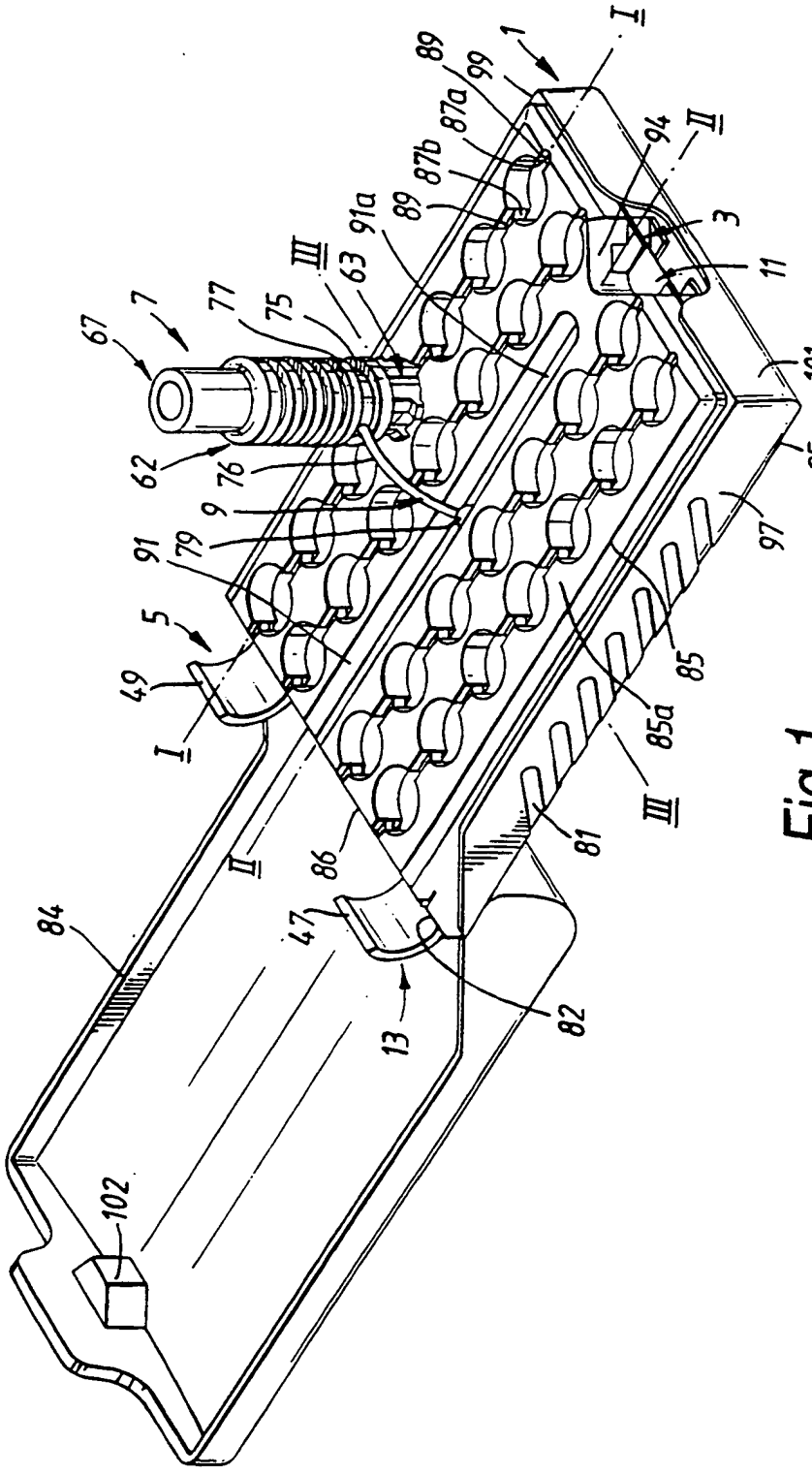

I
II
III
1
89
99
87a
87b
91a
63
77
75
67
7
62
76
9
91
79
5
49
94
3
11
101
95
97
85
85a
81
86
47
84
82
13
102

Fig.1

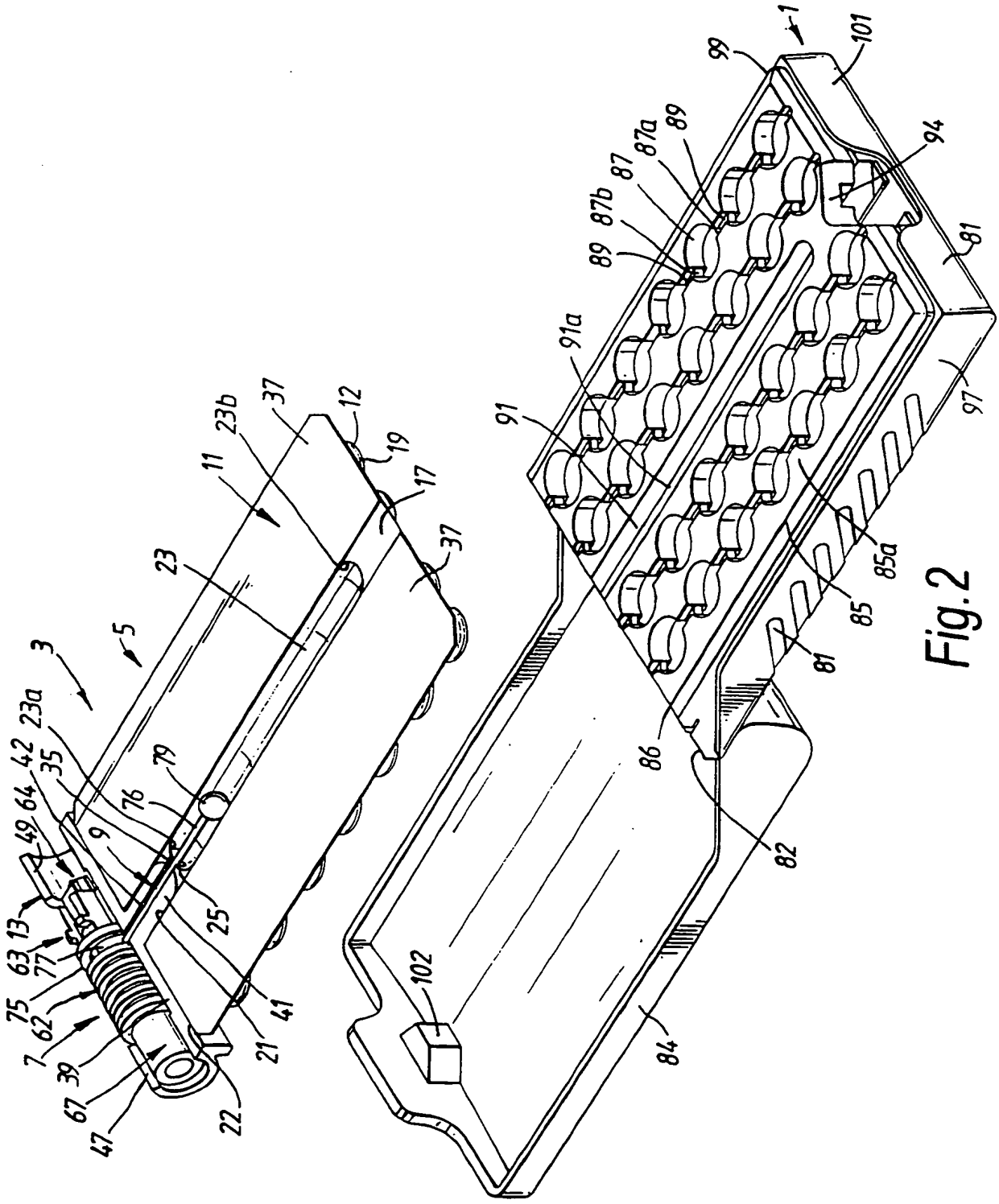

1
101
99
94
89
87a
87
87b
89
81
91a
91
97
85a
85
81
86
82
84
102
3
5
23a
42
35
64
49
13
63
77
75
62
7
39
67
47
22
21
41
25
9
76
79
23
11
23b
37
12
19
17
37

Fig.2

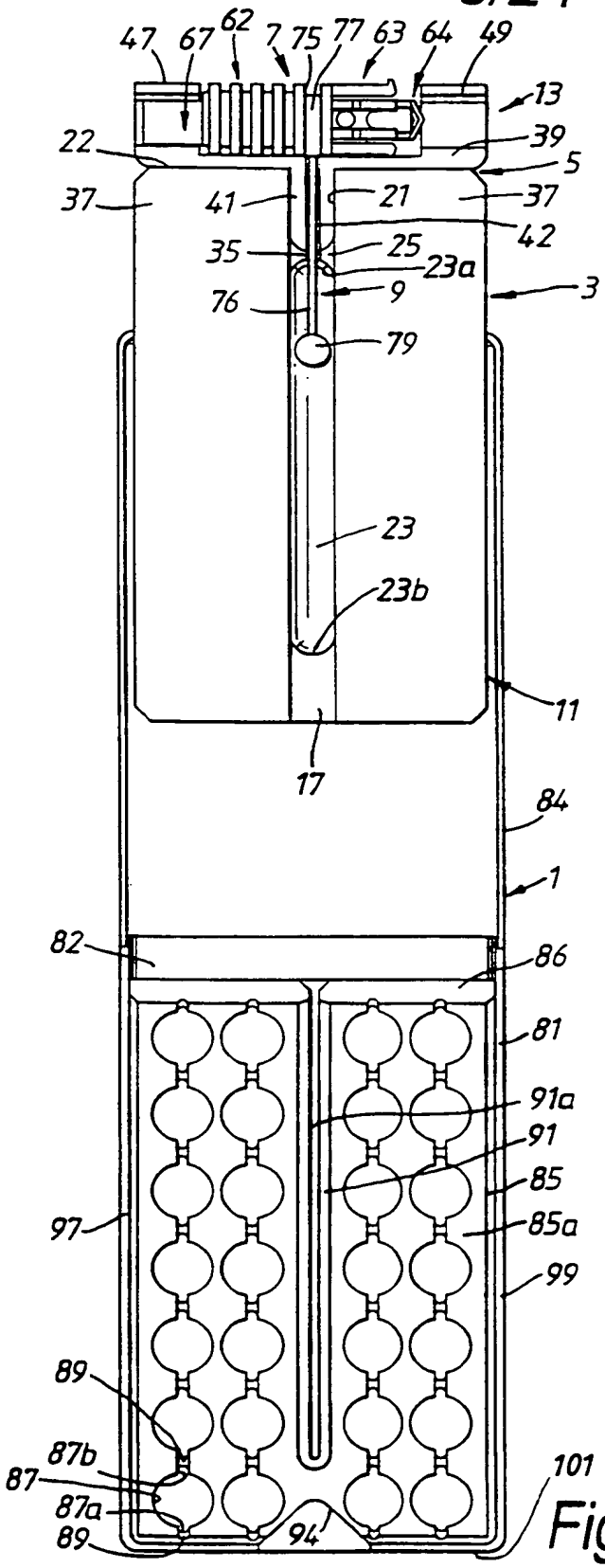

47
67
62
7
75
77
63
64
49
13
22
39
5
37
41
21
37
42
35
25
23a
3
76
9
79
23
23b
11
17
84
1
82
86
81
91a
91
85
97
85a
99
89
87b
87
87a
89
94
101

Fig.3

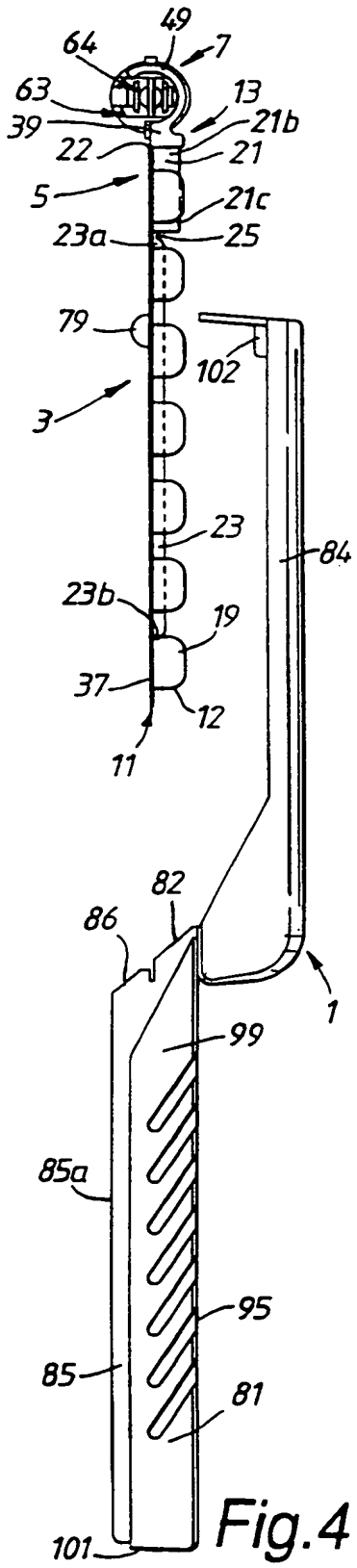

49
64
7
63
13
39
21b
22
21
5
21c
23a
25
79
102
3
23
84
23b
19
37
12
11
82
86
1
99
85a
95
85
81
101

Fig.4

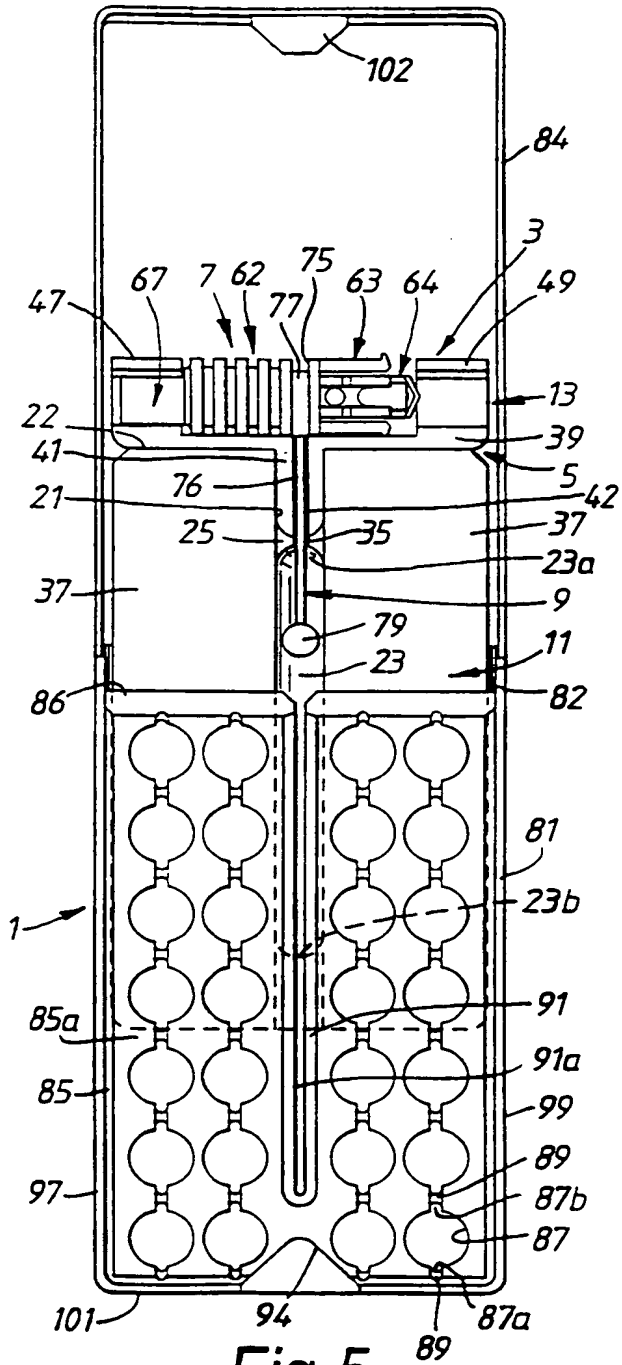

102
84
3
67
7
62
75
63
64
49
47
77
13
22
39
41
5
76
42
21
25
35
37
23a
37
9
79
11
23
86
82
81
1
23b
91
85a
91a
85
99
89
97
87b
87
101
94
87a
89

Fig.5

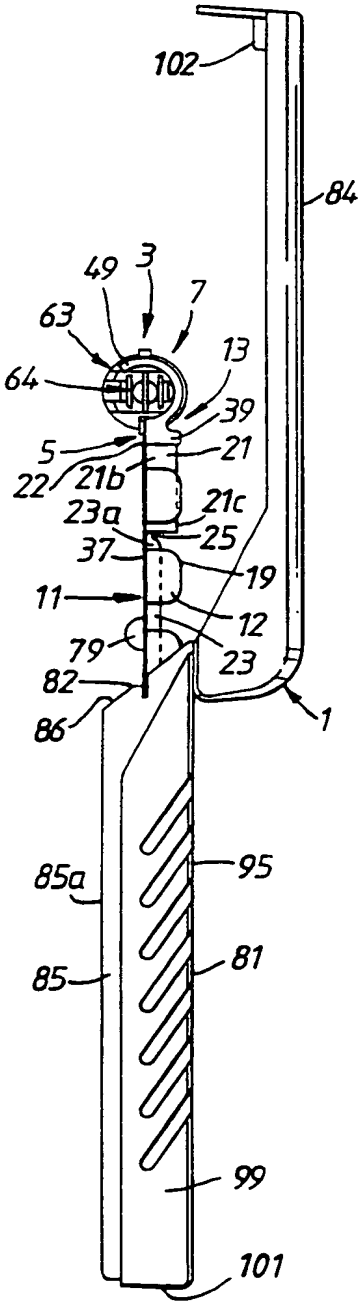

102
84
49
3
7
63
13
64
39
5
21
22
21b
21c
23a
25
37
19
11
12
79
23
82
86
1
85a
95
85
81
99
101

Fig.6

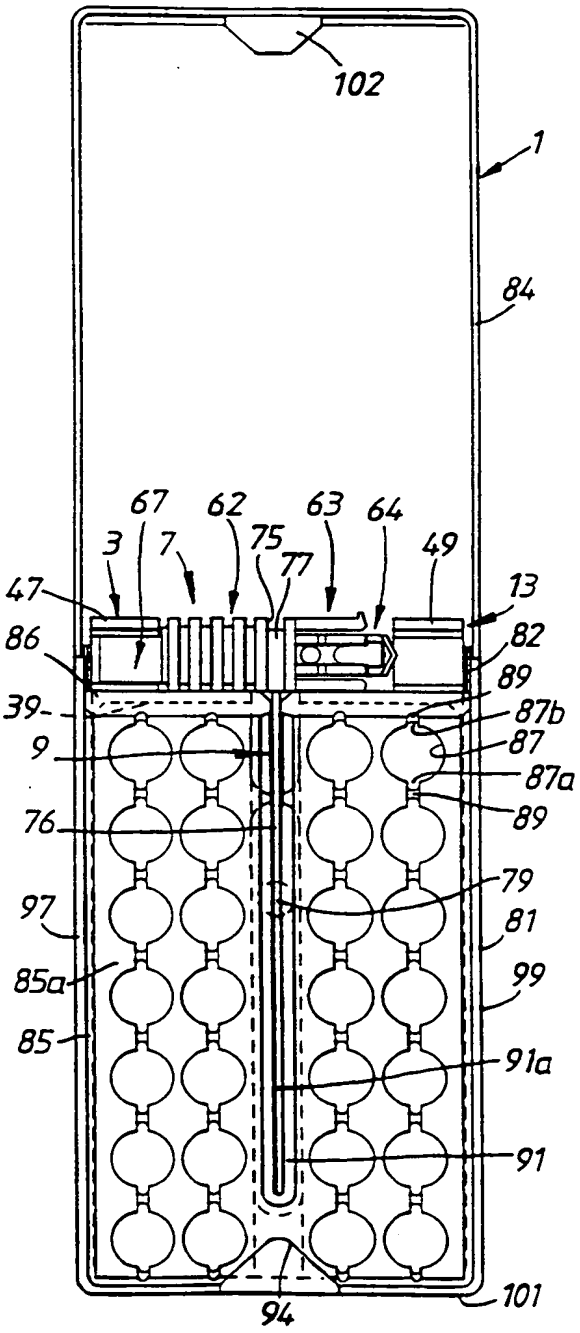

102
1
84
67
62
63
64
3
7
75
77
49
47
13
86
82
89
39
87b
9
87
87a
76
89
79
97
81
85a
99
85
91a
91
101
94

Fig.7

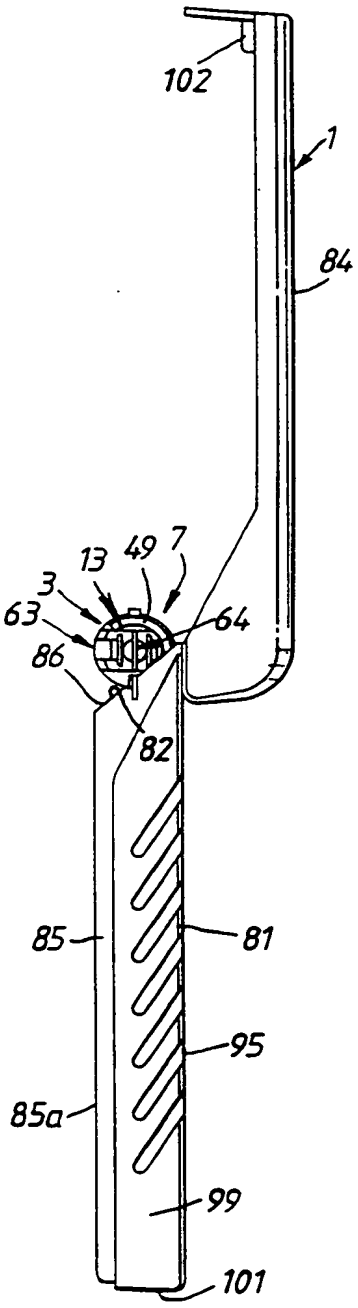

102
1
84
13
49
7
3
63
64
86
82
85
81
95
85a
99
101

Fig.8

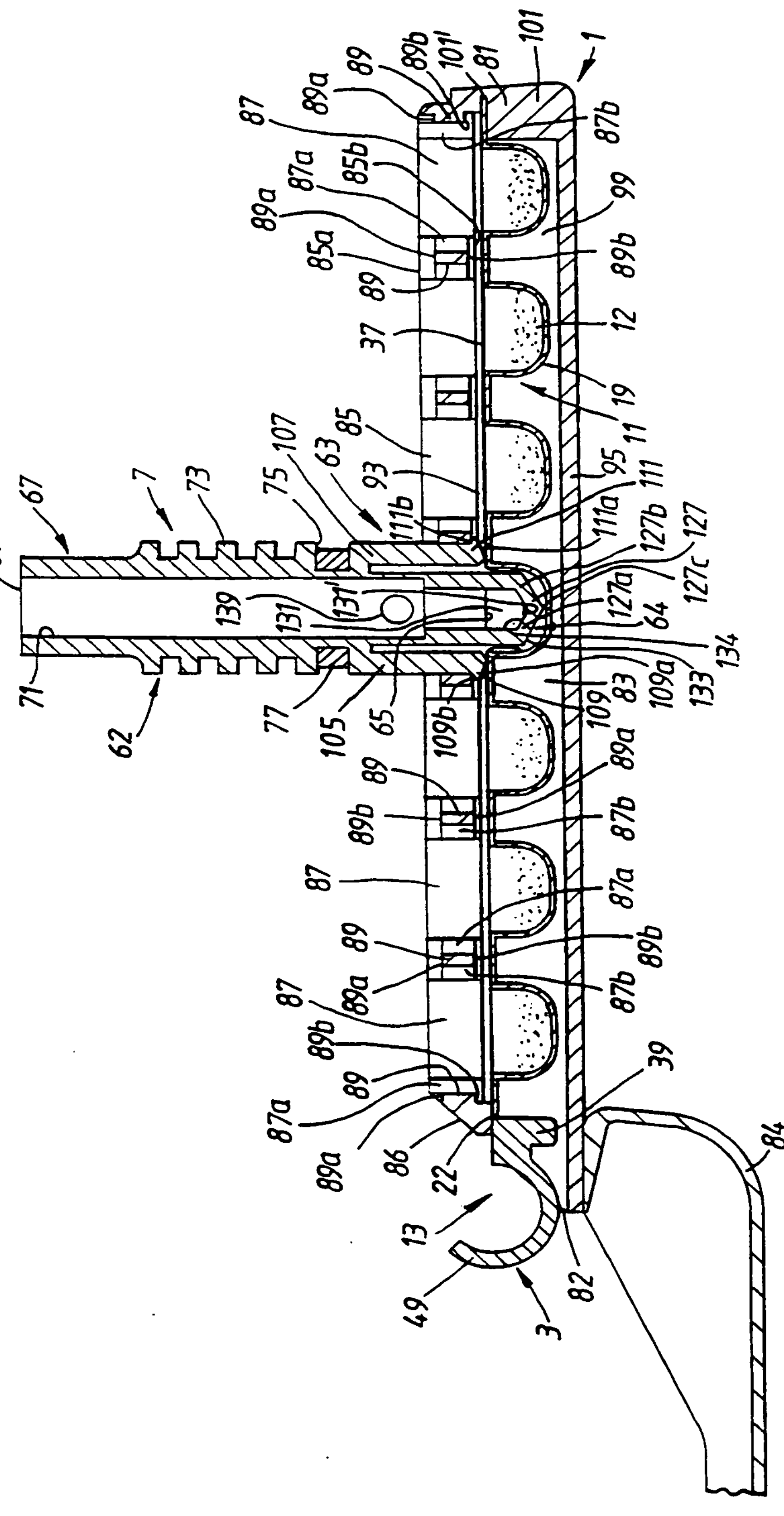


Fig.9

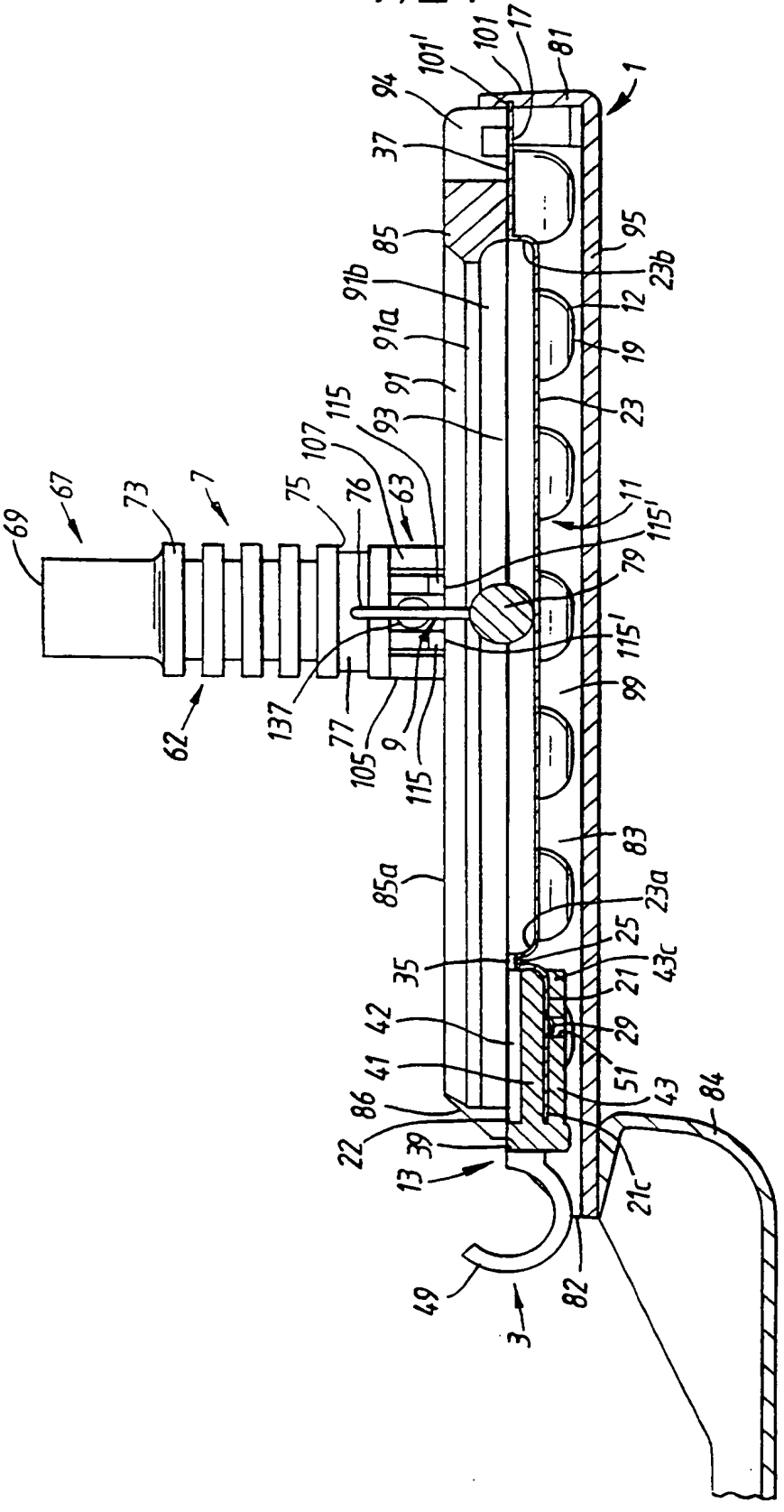

1
101'
101
17
81
94
37
85
95
91b
23b
12
91a
19
91
23
93
115
107
75
76
63
7
73
67
69
11
115'
79
115'
99
137
77
105
9
115
62
83
85a
23a
25
43c
35
21
42
29
41
51
43
86
84
22
39
13
21c
49
82
3

Fig.10

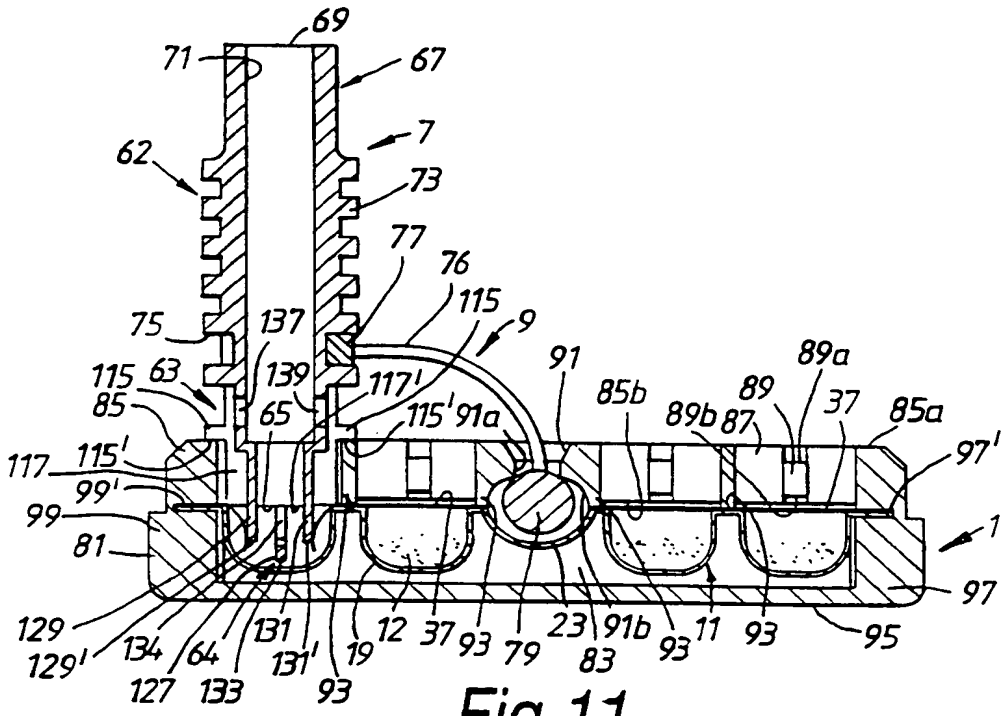

69
71
67
7
62
73
77
76
115
9
75
137
139
117'
115'
91a
91
85b
89b
89
87
89a
37
85a
63
115
85
65
117
115'
99'
99
81
97'
1
97
129
129'
134
64
127
133
131
131'
19
93
12
37
93
79
23
83
91b
93
11
93
95

Fig.11

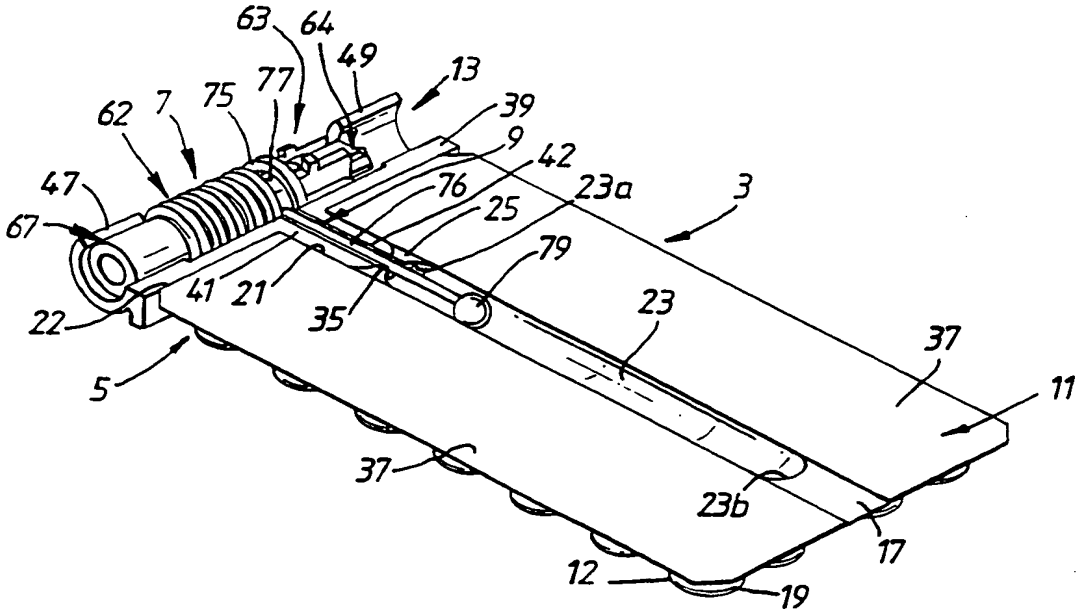

63
64
49
13
77
75
7
62
39
9
42
23a
3
47
67
76
25
79
41
21
35
23
37
11
22
5
37
23b
17
12
19

Fig.12

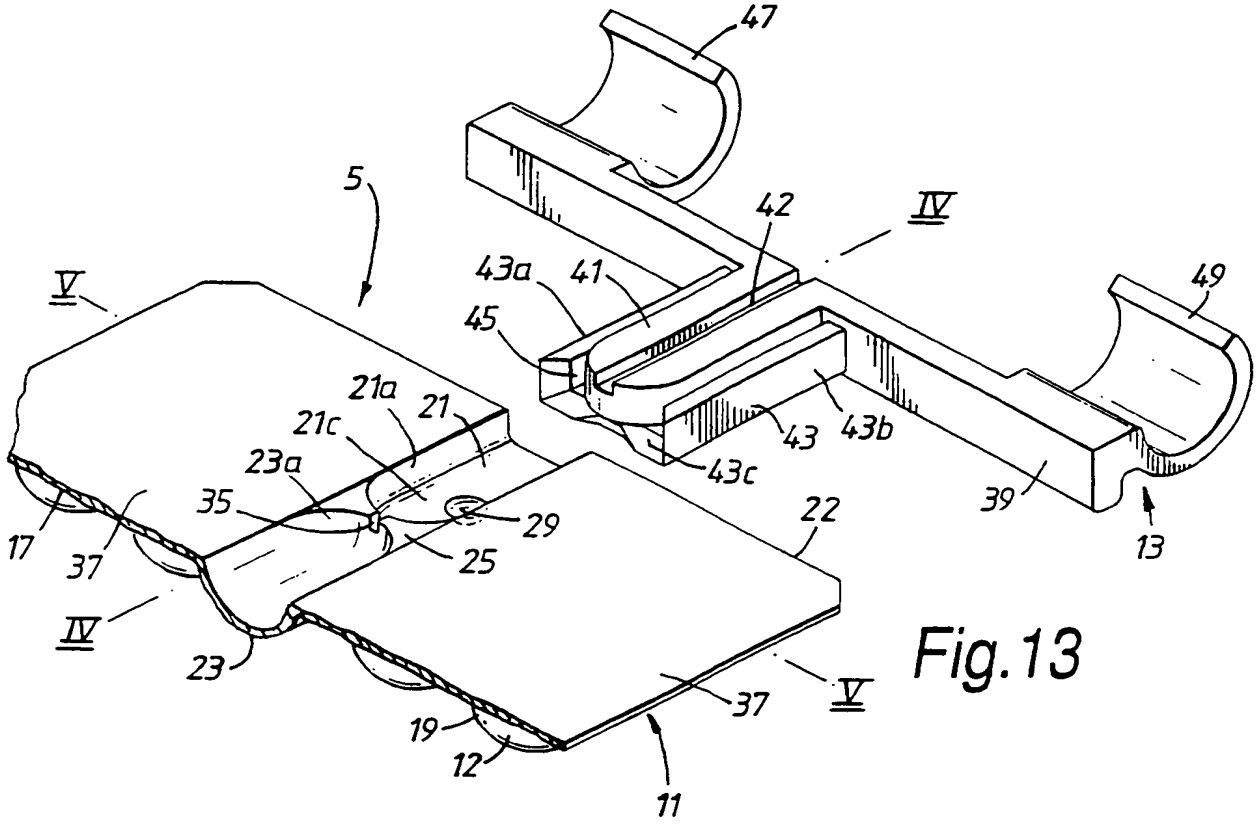


Fig.13

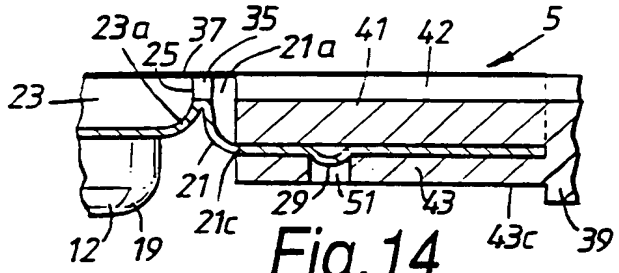


Fig.14

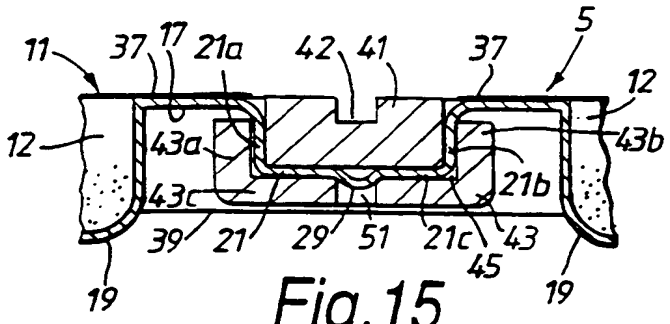


Fig.15

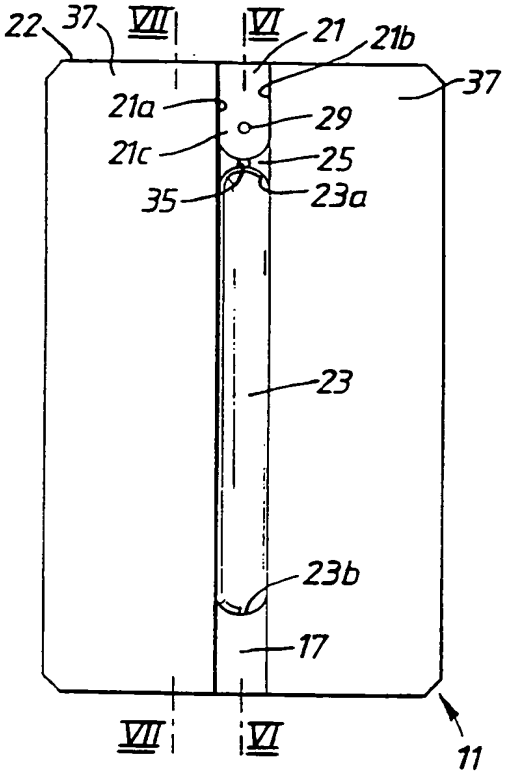


Fig.16(a)

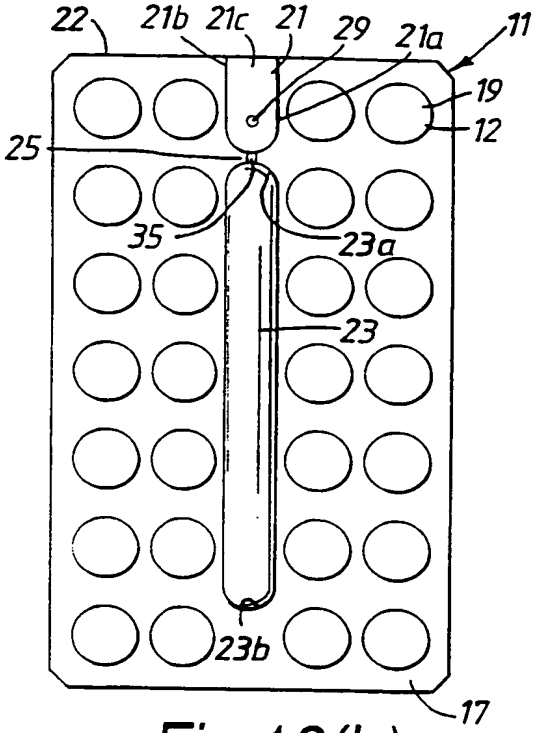


Fig.16(b)

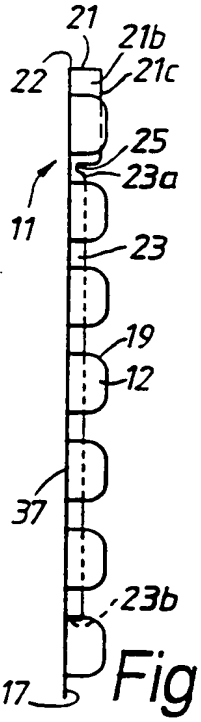


Fig.16(c)

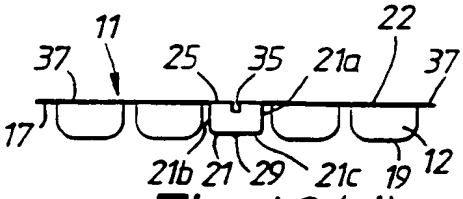


Fig.16(d)

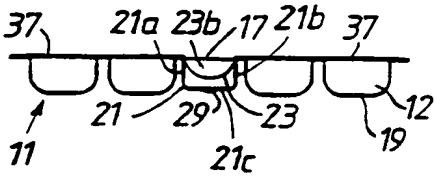


Fig.16(e)

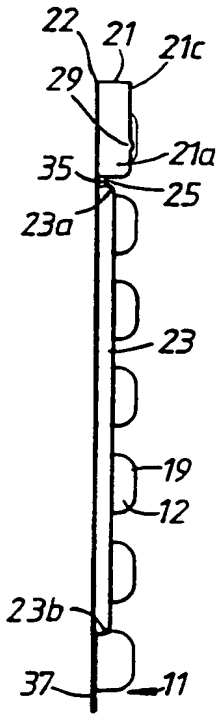


Fig.16(f)

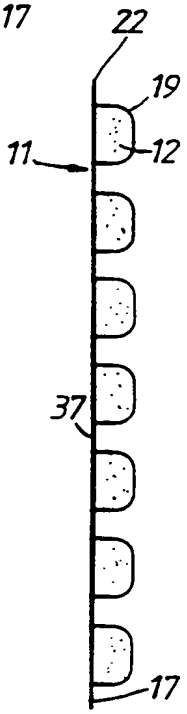


Fig.16(g)

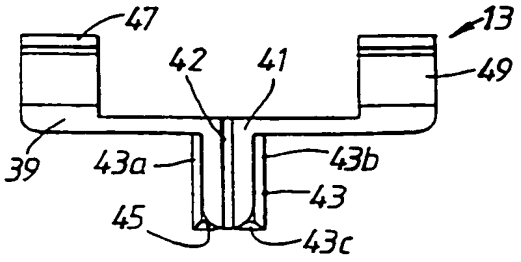


Fig.17(a)

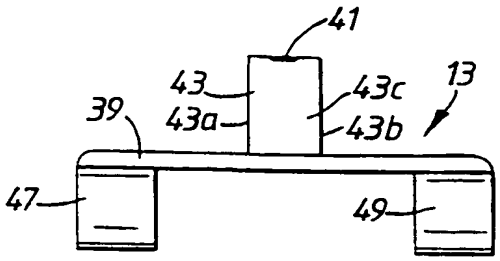


Fig.17(b)

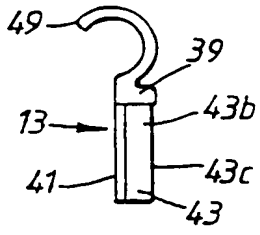


Fig.17(c)

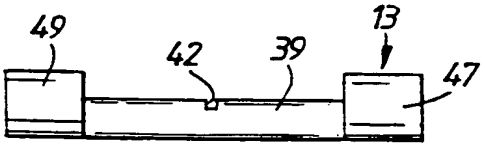


Fig.17(d)

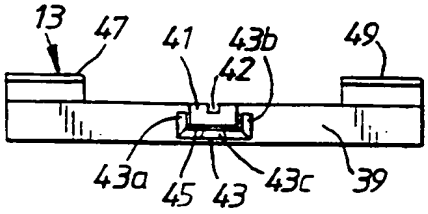


Fig.17(e)

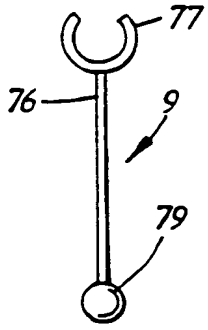


Fig.19(a)

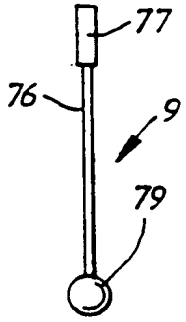


Fig.19(b)

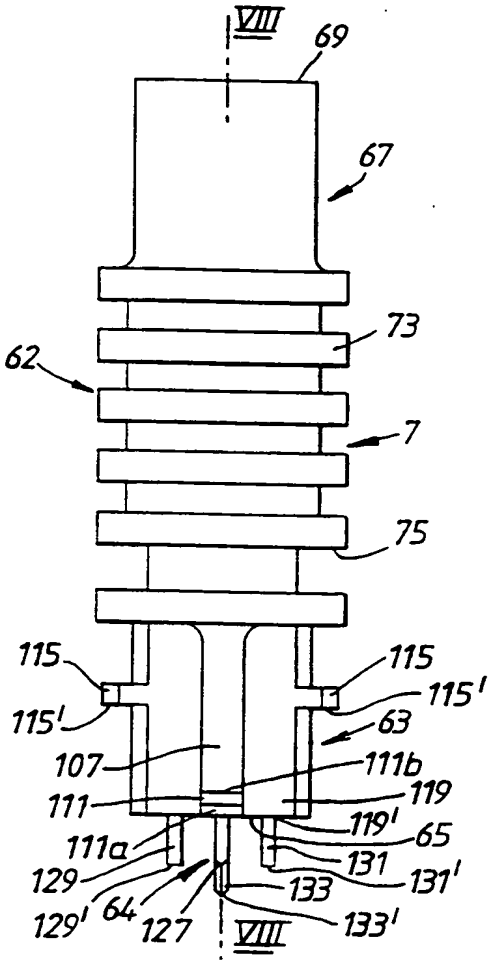


Fig.18(a)

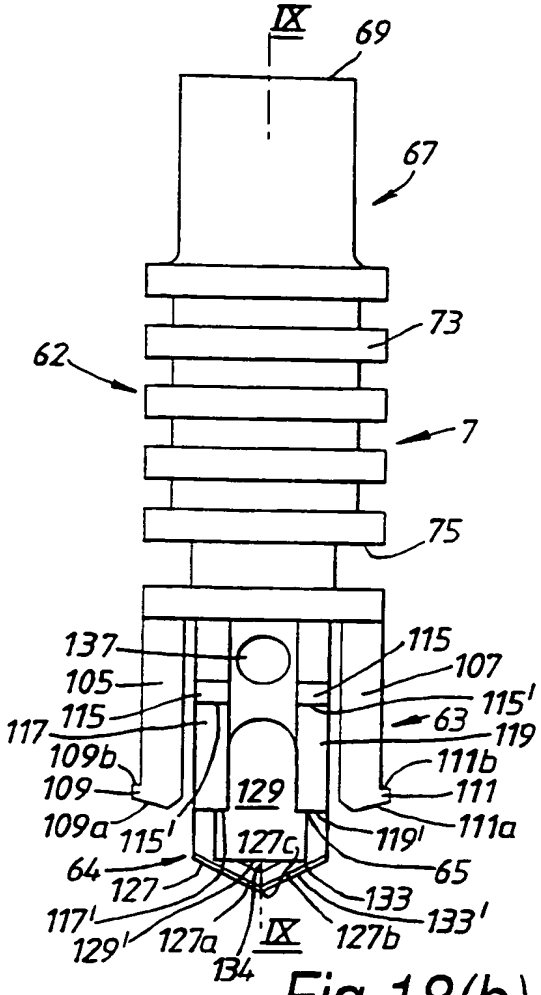


Fig.18(b)

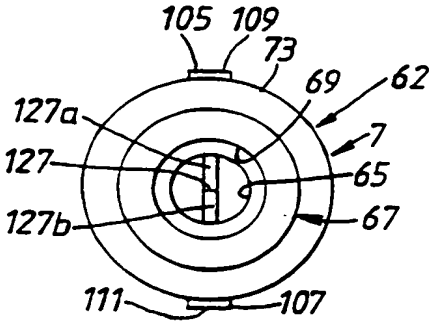


Fig.18(c)

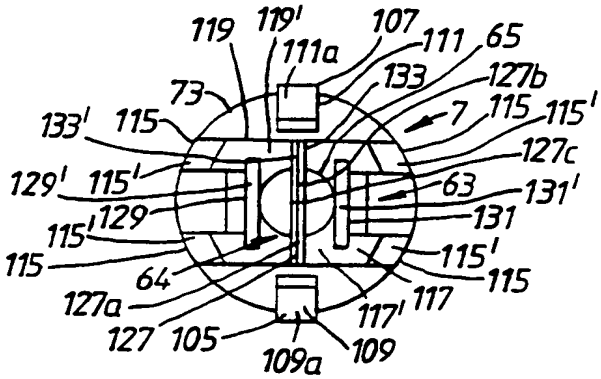


Fig.18(d)

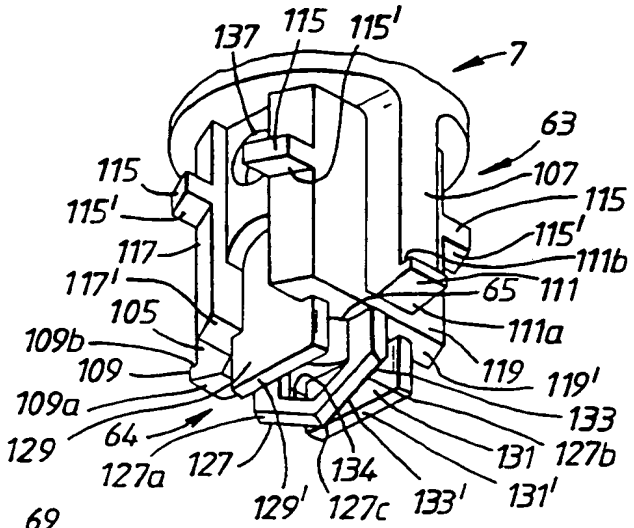


Fig.18(e)

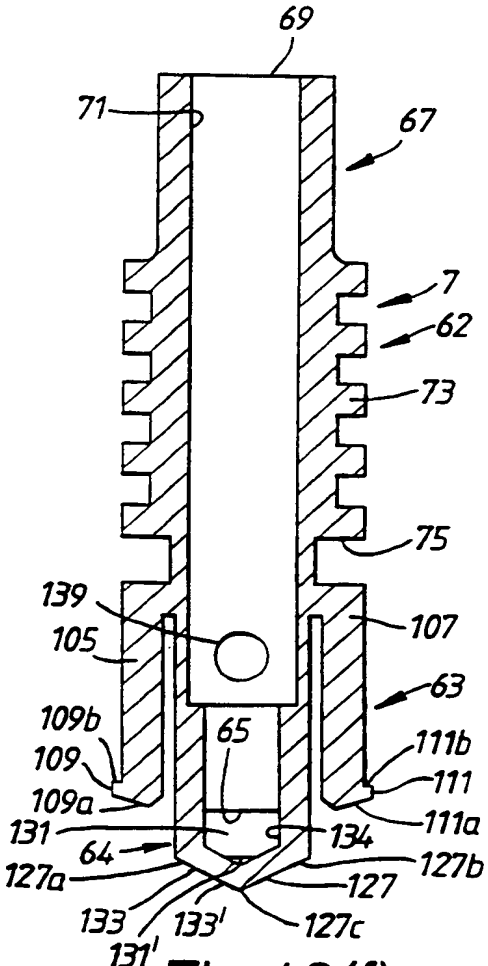


Fig.18(f)

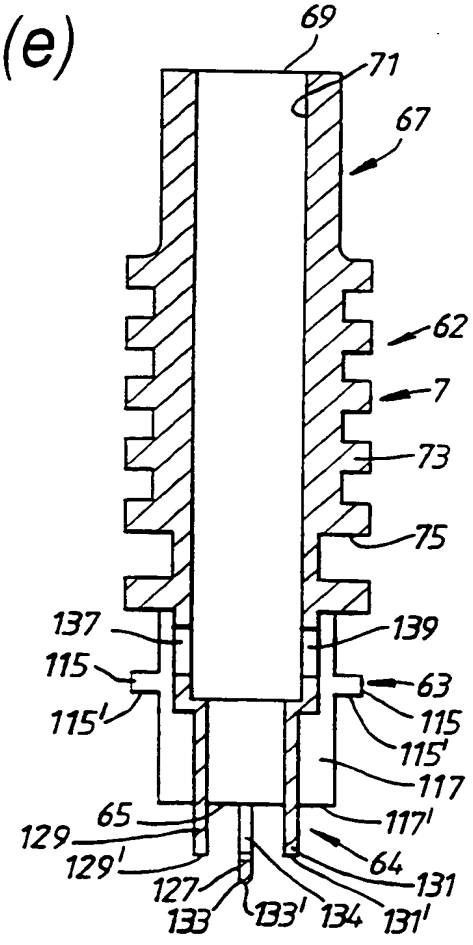


Fig.18(g)

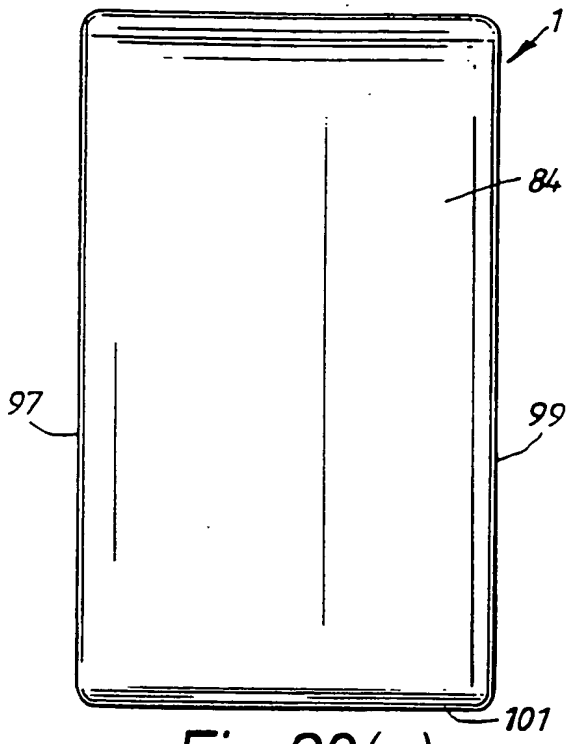


Fig.20(a)

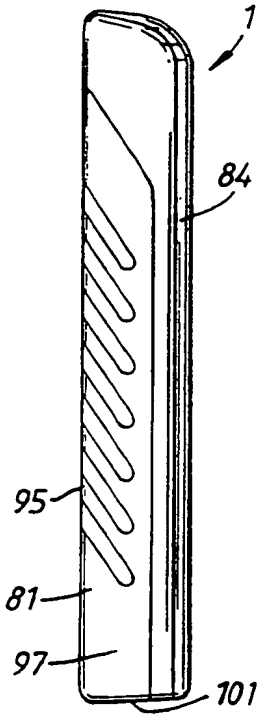


Fig.20(b)

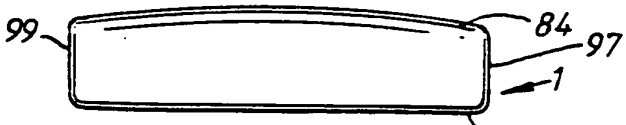


Fig.20(c)

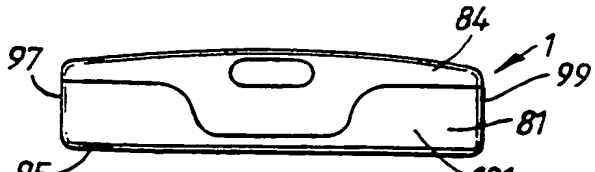


Fig.20(d)

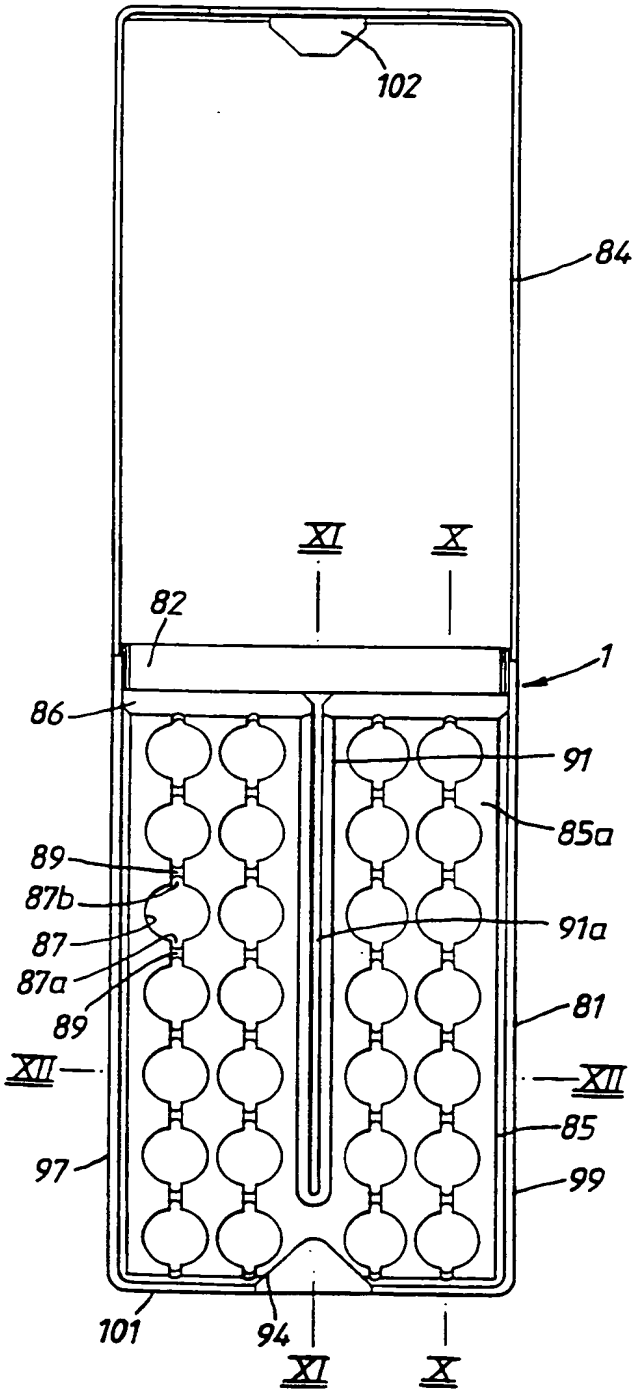


Fig.20(e)

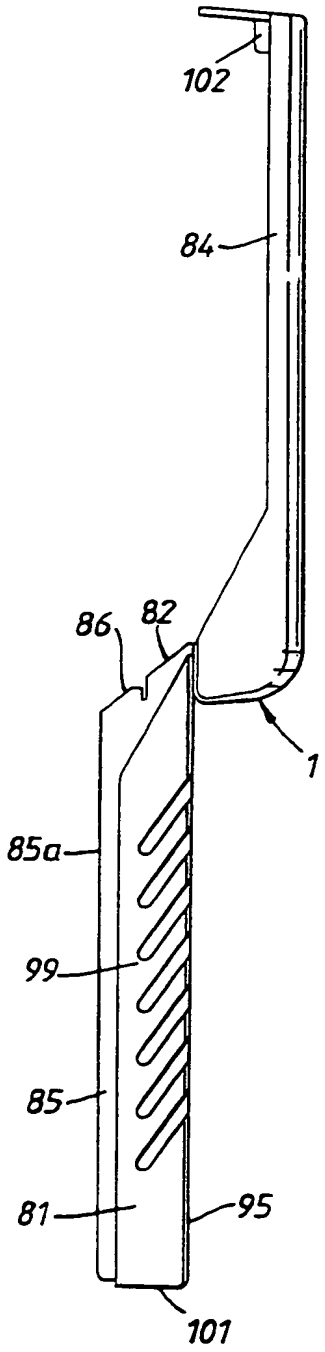


Fig.20(f)

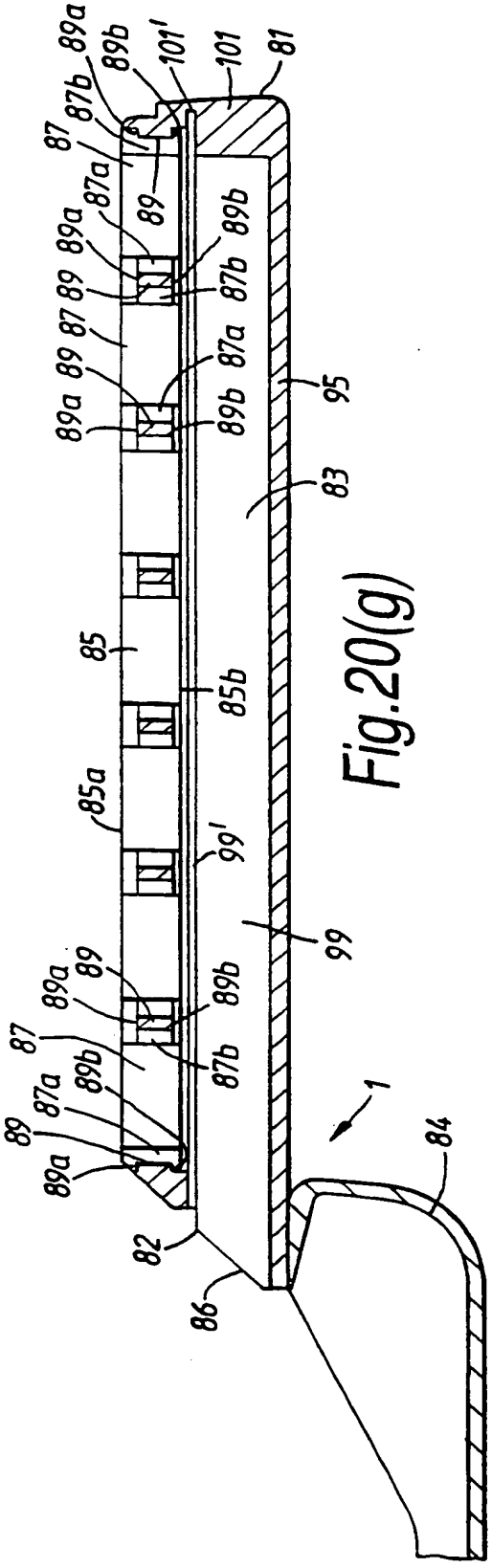


Fig.20(g)

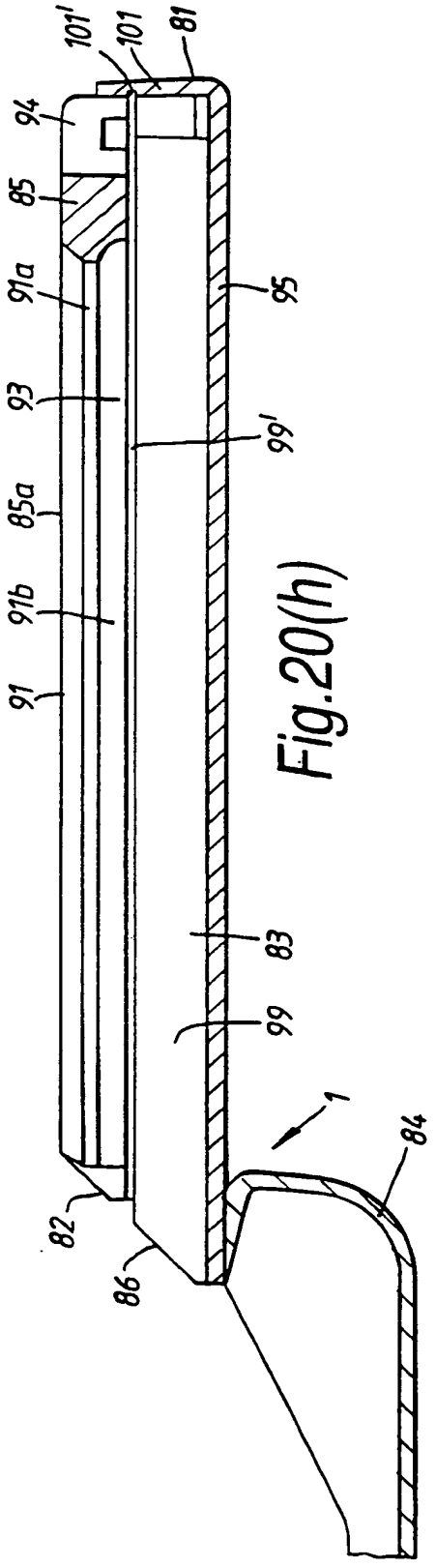


Fig.20(h)

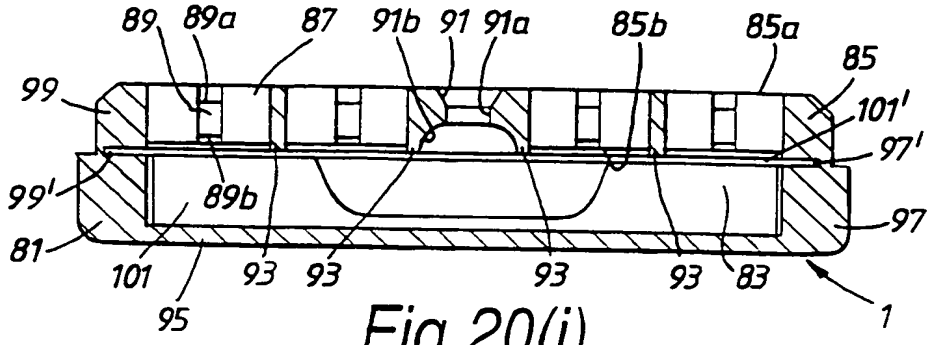


Fig.20(i)

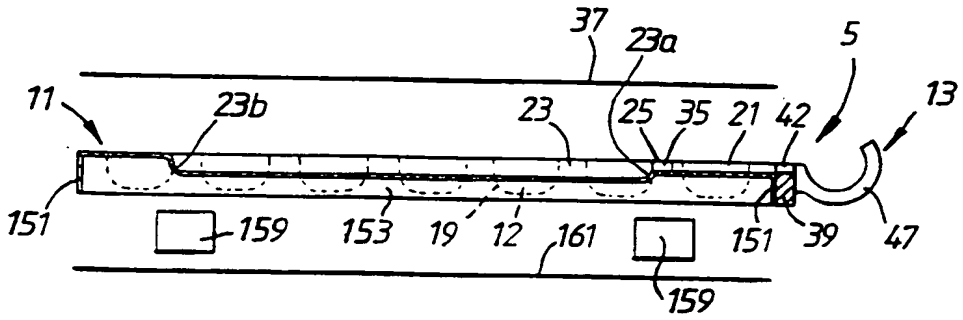


Fig.31

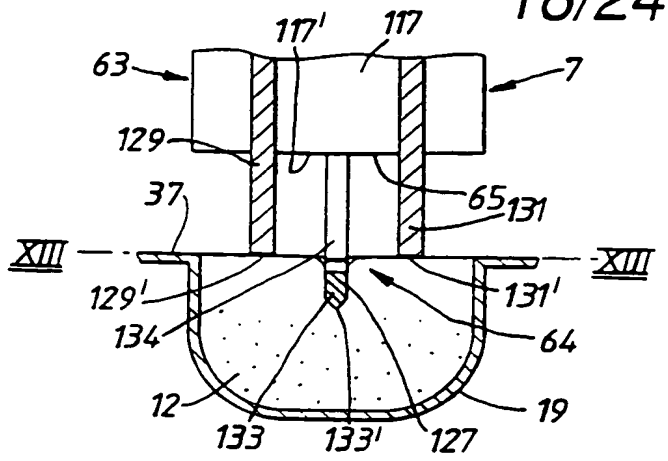


Fig.21(a)

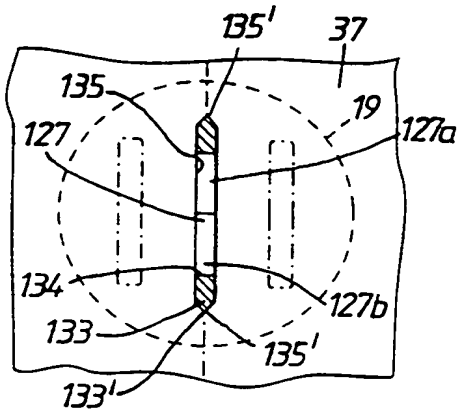


Fig.21(b)

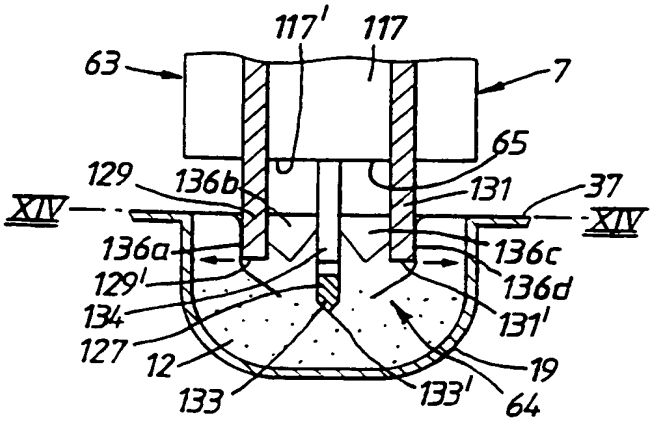


Fig.22(a)

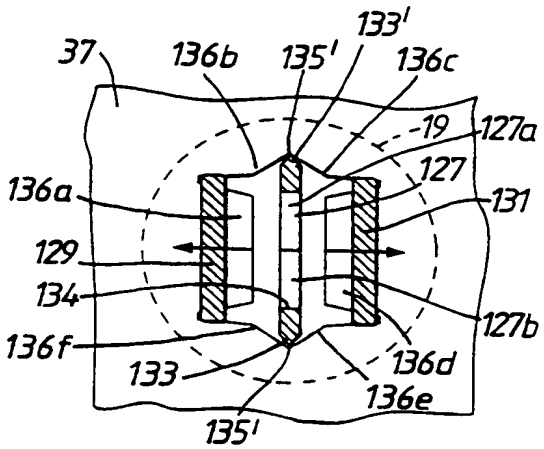


Fig.22(b)

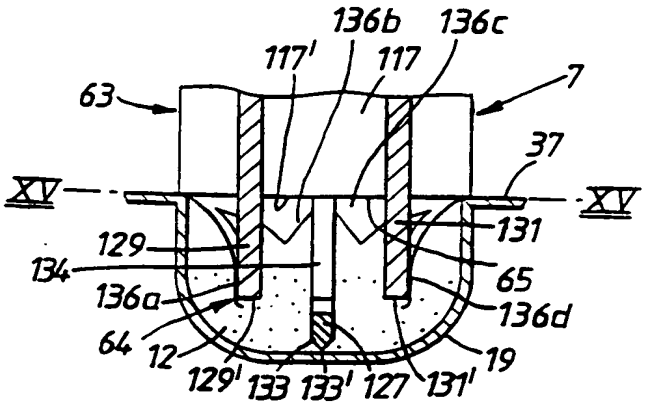


Fig.23(a)

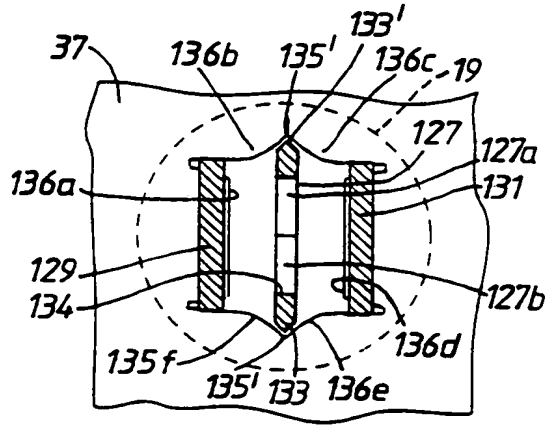


Fig.23(b)

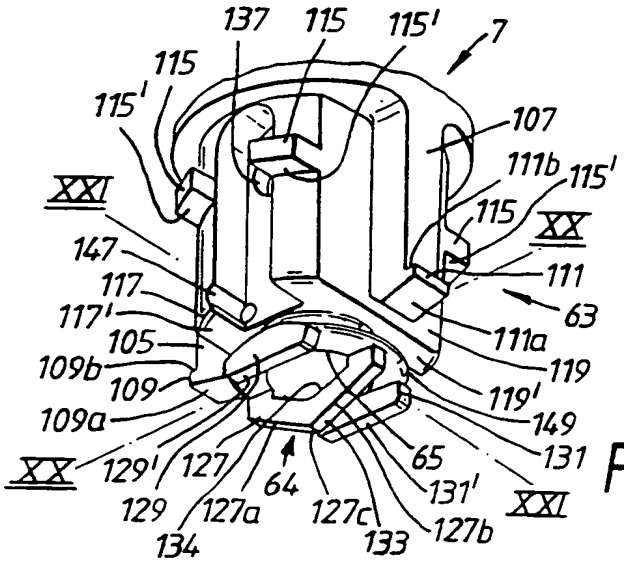


Fig.24(a)

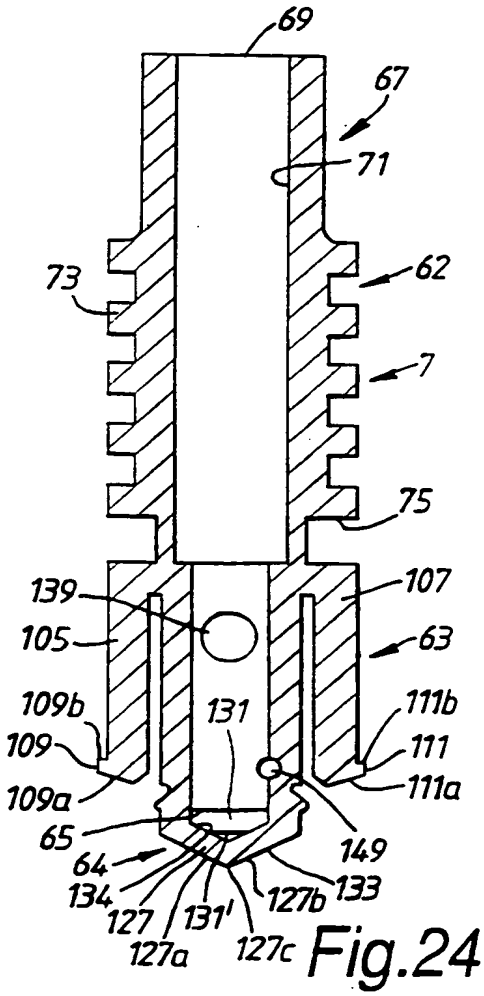


Fig.24(b)

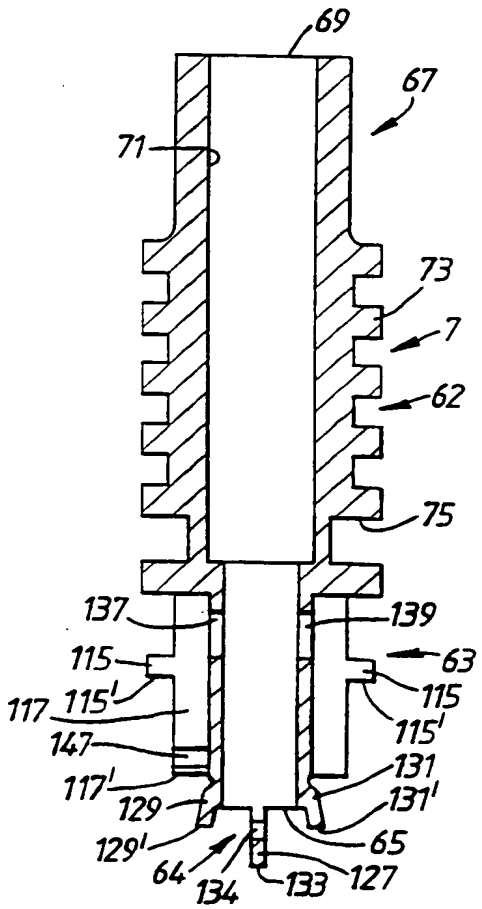


Fig.24(c)

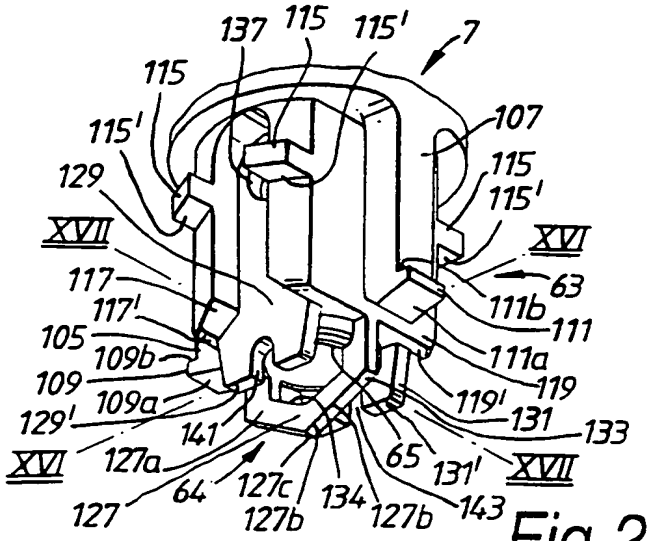


Fig.25(a)

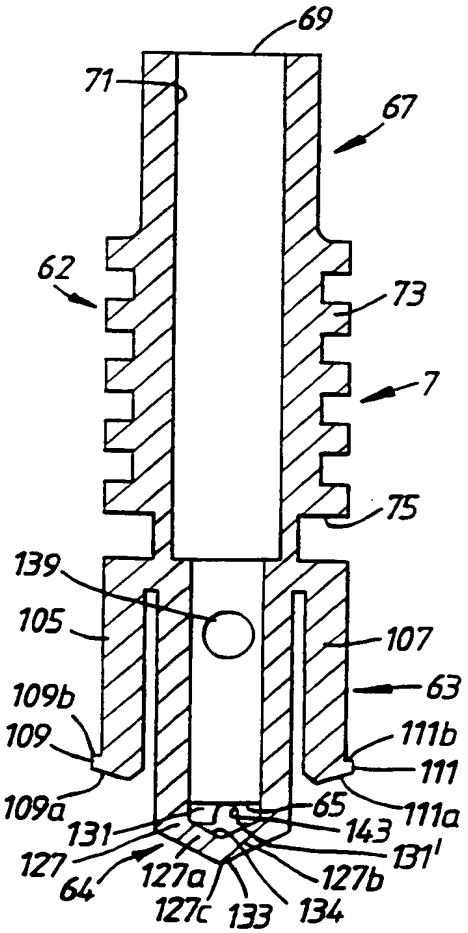


Fig.25(b)

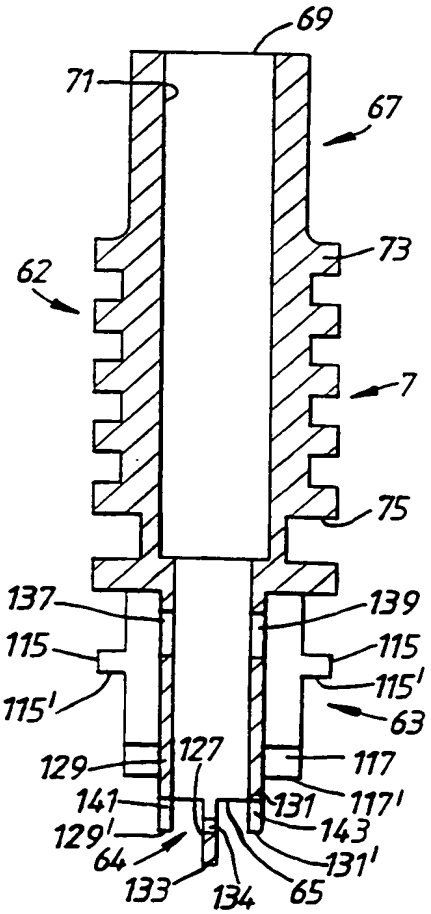


Fig.25(c)

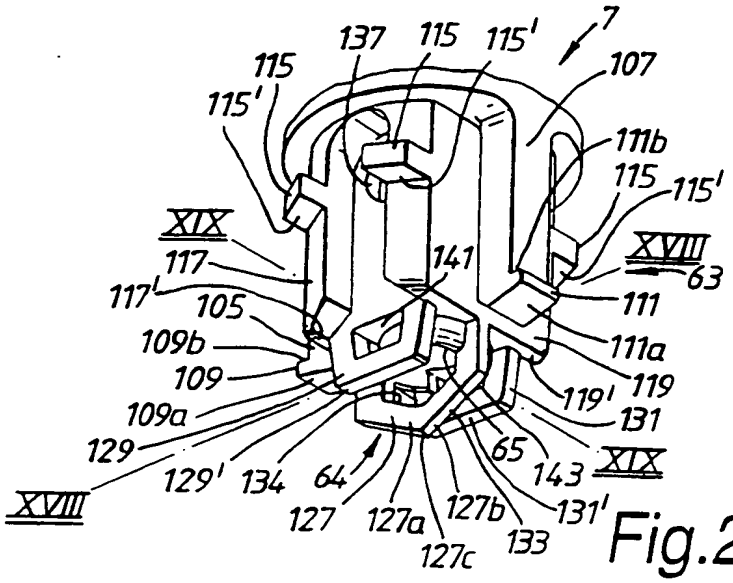


Fig.26(a)

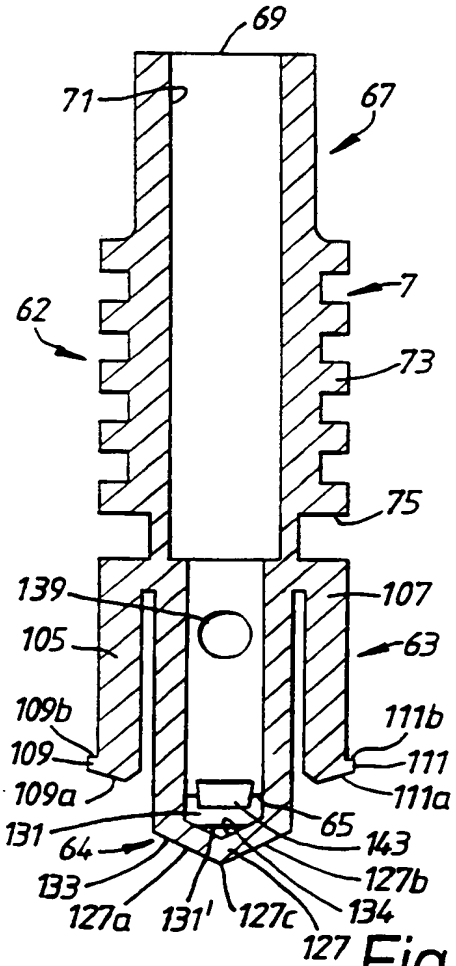


Fig.26(b)

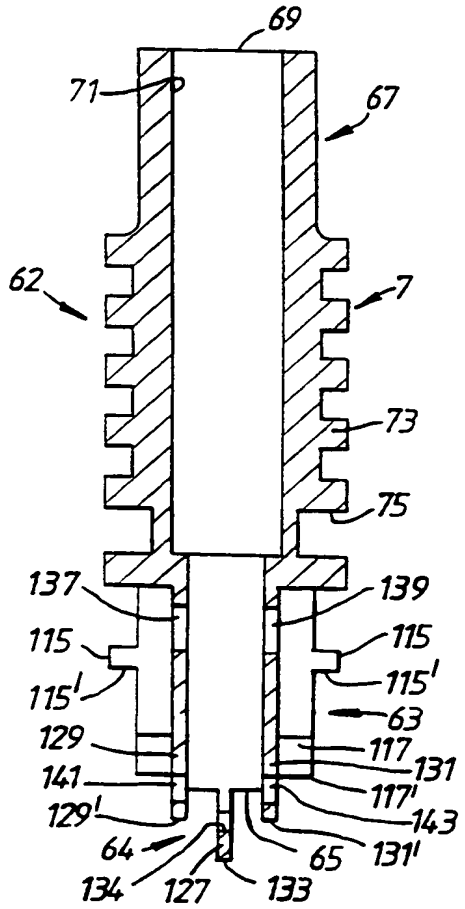


Fig.26(c)

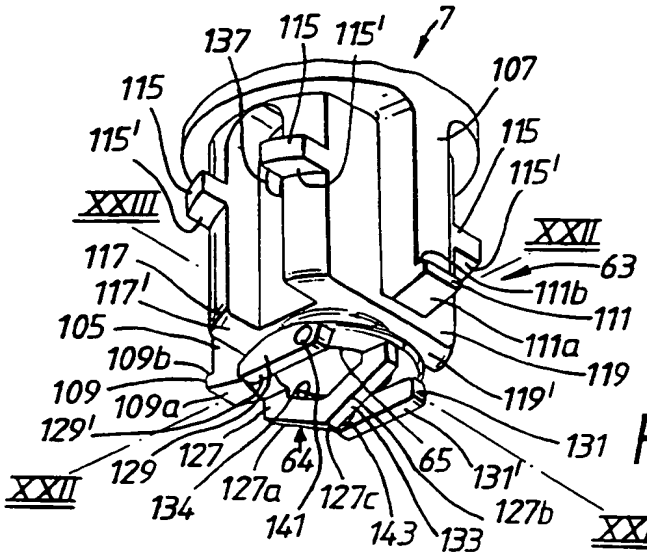


Fig.27(a)

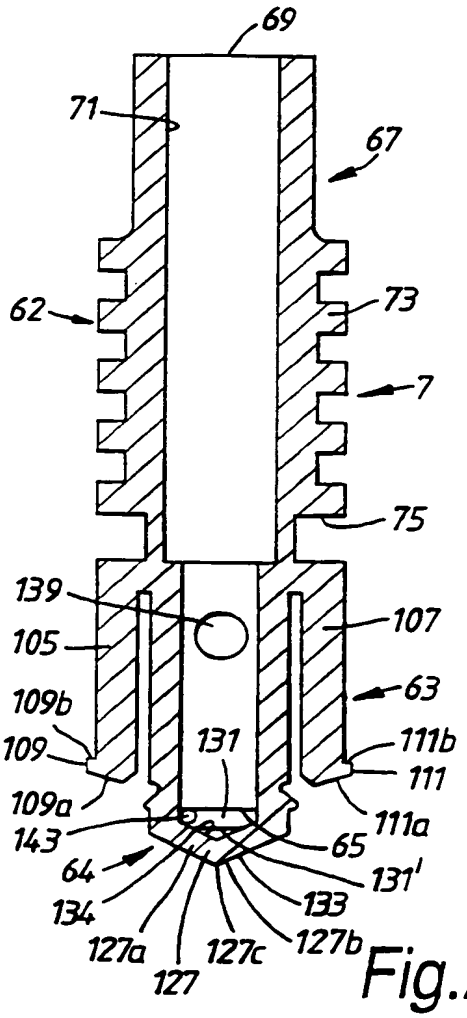


Fig.27(b)

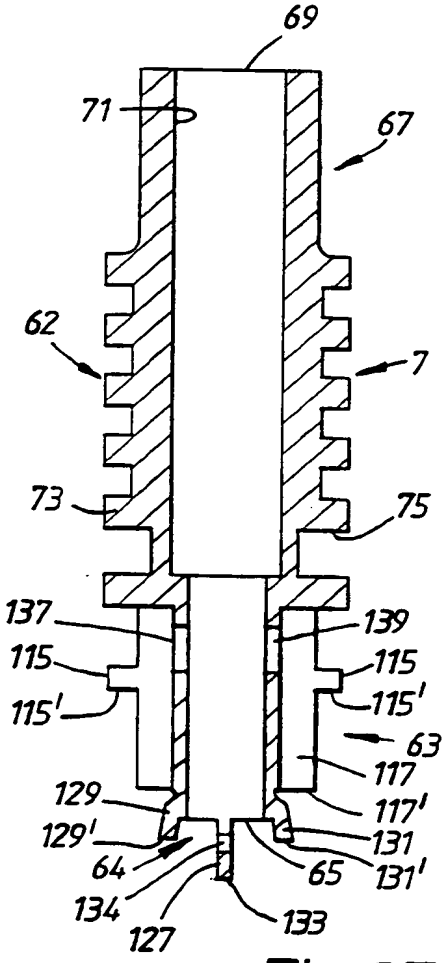


Fig.27(c)

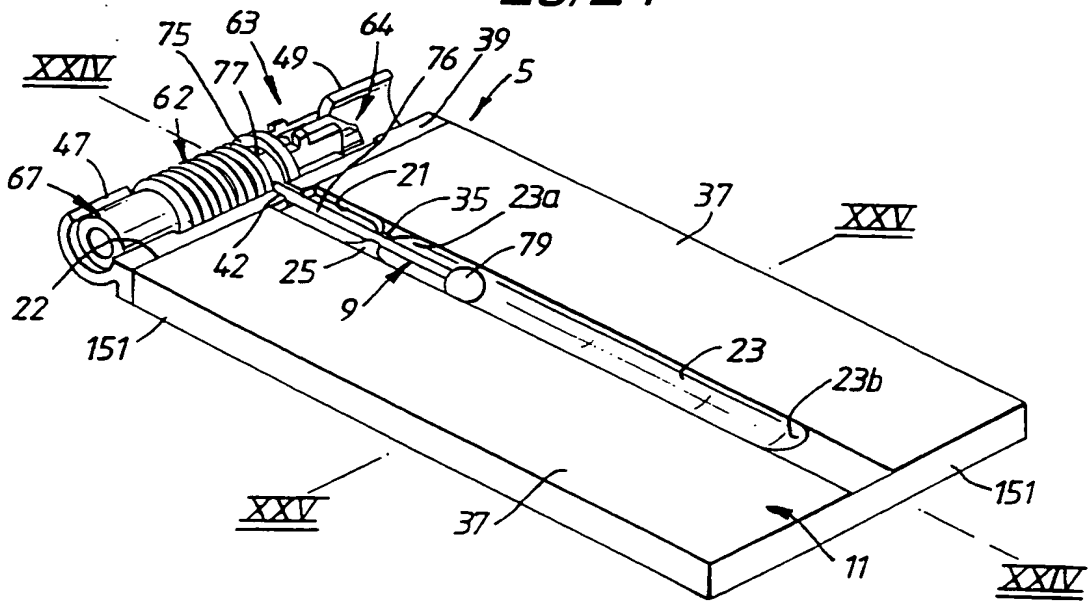

XXIV
75
63
64
49
77
76
39
5
62
47
67
21
35
23a
37
XXV
42
25
79
9
22
151
23
23b
151
XXV
37
11
XXIV

Fig.28

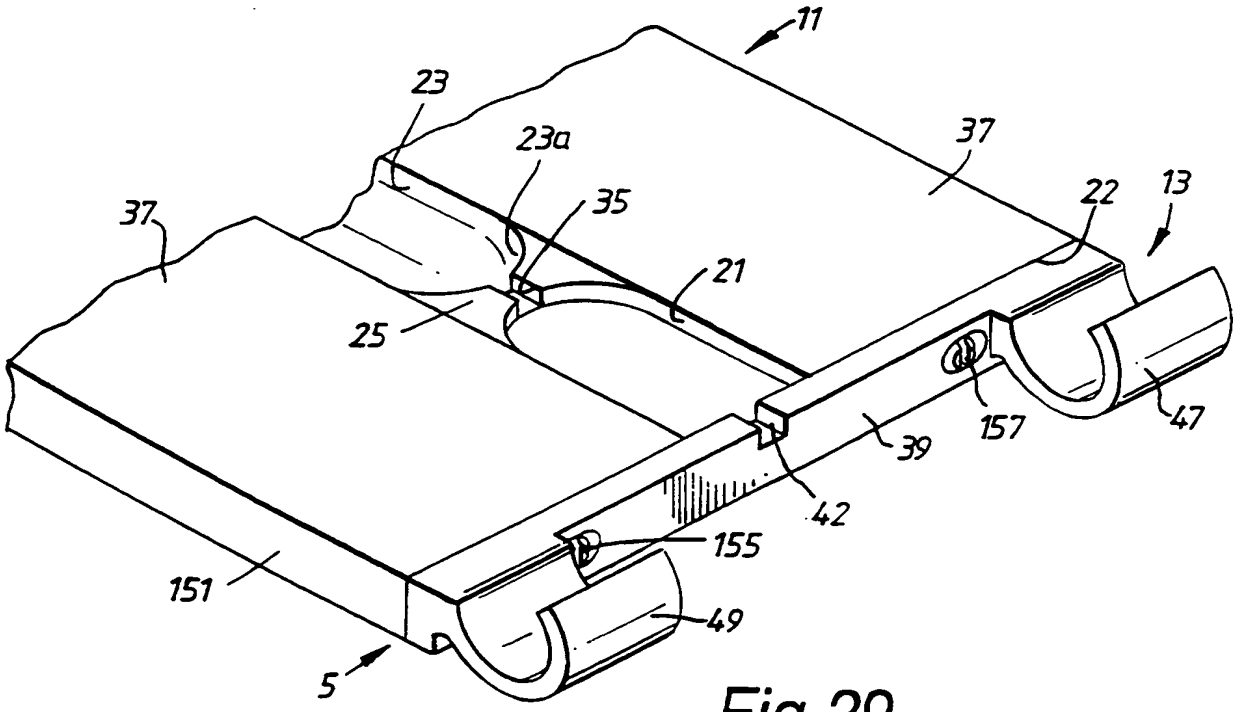

11
23
23a
37
37
35
22
13
21
25
157
47
39
42
155
151
49
5

Fig.29

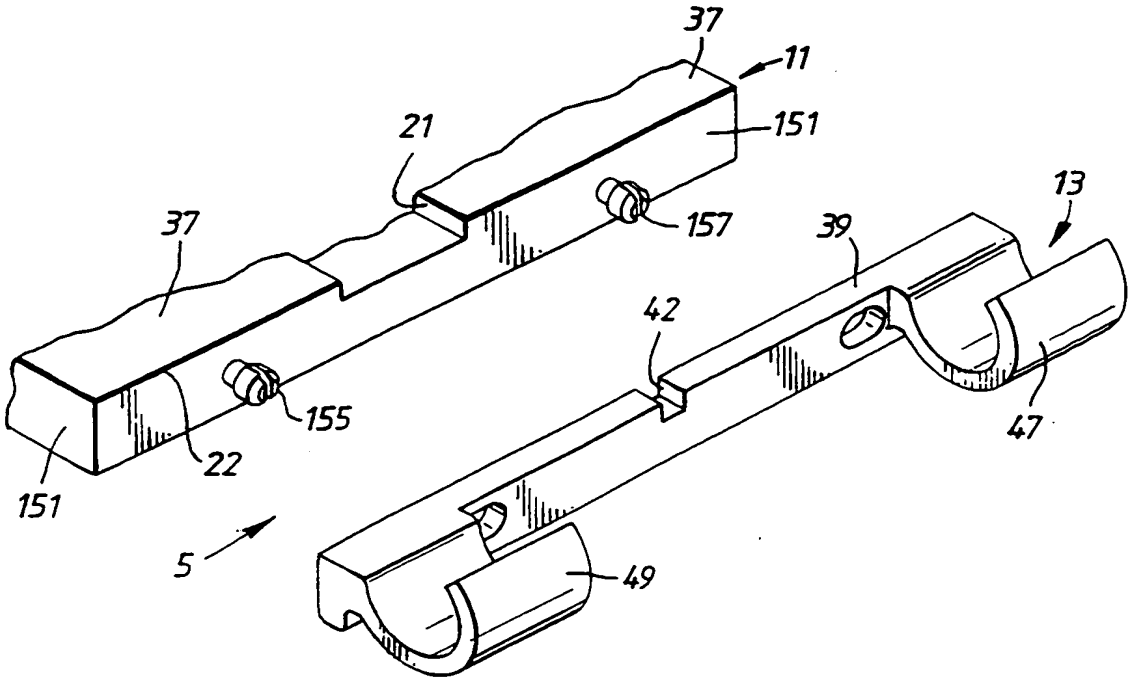

37
11
21
151
13
37
157
39
42
155
47
22
151
5
49

Fig.30

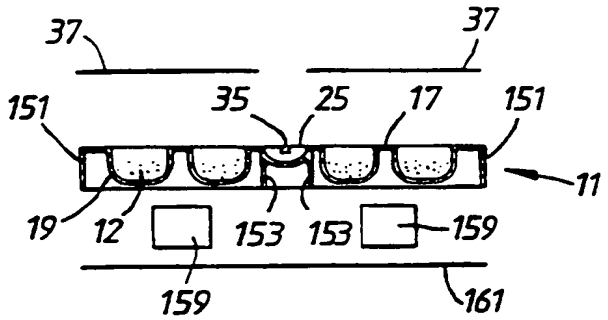

37
37
151
35
25
17
151
11
19
12
153
153
159
159
161

Fig.32

INTERNATIONAL SEARCH REPORT

ational Application No
PCT/EP 98/08454

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 40876 A (SCHUCKMANN ALFRED VON) 6 November 1997 cited in the application see page 2, line 7 - line 20 see page 18, line 11 - line 17 see page 20, line 12 - page 22, line 6 see page 23, line 4 - line 20 see page 24, line 14 - line 24 see figures 4,5,10,14	1-8,16, 20-27
A	WO 96 09085 A (INHALE THERAPEUTIC SYST) 28 March 1996 see page 21, line 34 - page 22, line 2 see page 3, line 25 - line 28 see page 35, line 10 - line 16 see figures 16-19	1-8,17, 18

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 May 1999	27/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, A

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category '	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 533 502 A (PIPER SAMUEL D) 9 July 1996 see column 2, line 22 - line 58 see column 4, line 40 - line 58 see column 5, line 4 - line 19 see figures 1,3	
A	WO 92 00812 A (PFEIFFER ERICH GMBH & CO KG) 23 January 1992 see abstract see page 3, line 36 - page 4, line 4 see page 8, line 9 - line 27 see figure 2	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 98/08454

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9740876 A	06-11-1997	DE 19619536 A	30-10-1997
		AU 2771997 A	19-11-1997
		NO 984944 A	23-10-1998
WO 9609085 A	28-03-1996	US 5785049 A	28-07-1998
		US 5740794 A	21-04-1998
		AU 697676 B	15-10-1998
		AU 3553295 A	09-04-1996
		BR 9508964 A	02-06-1998
		CA 2200727 A	28-03-1996
		CN 1160358 A	24-09-1997
		CZ 9700723 A	12-11-1997
		EP 0846009 A	10-06-1998
		FI 971173 A	20-03-1997
		HU 77691 A	28-07-1998
		JP 10508790 T	02-09-1998
		NO 971316 A	20-05-1997
		NZ 293163 A	24-09-1998
		PL 319505 A	18-08-1998
		ZA 9507933 A	02-08-1996
US 5533502 A	09-07-1996	NONE	
WO 9200812 A	23-01-1992	DE 4021263 A	16-01-1992
		AT 166004 T	15-05-1998
		AU 8073991 A	04-02-1992
		DE 59108987 D	18-06-1998
		EP 0591182 A	13-04-1994
		EP 0827782 A	11-03-1998
		ES 2116293 T	16-07-1998
		US 5469989 A	28-11-1995
		US 5584417 A	17-12-1996